The Heart of the Matter

Chronic Disease Prevention Guidance and Resources for WISEWOMAN Projects

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

WISEWOMAN

CDC Chronic Disease Prevention

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Abbreviations and Acronyms

Below is a list of abbreviations and acronyms that are commonly used in the WISEWOMAN program.

A1c test	**Glycosolated hemoglobin test**
ADA	**American Diabetes Association**
ATP III	**National Cholesterol Education Program, Adult Treatment Panel III Report (National Cholesterol Education Program, 2001)**
BCCEDP	**State/tribal level activities sponsored by the National Breast and Cervical Cancer Early Detection Program**
BMI	**Body mass index**
CDC	**Centers for Disease Control and Prevention**
CLIA	**Clinical Laboratory Improvement Amendments**
CHD	**Coronary heart disease**
CVD	**Cardiovascular disease**
CVH	**Cardiovascular health**
DASH	**Dietary Approaches to Stop Hypertension**
DBP	**Diastolic blood pressure**
DCPC	**Division of Cancer Prevention and Control**
DDT	**Division of Diabetes Translation**
DHDSP	**Division for Heart Disease and Stroke Prevention**
DHHS	**Department of Health and Human Services**
DNPA	**Division of Nutrition and Physical Activity**
FPG test	**Fasting plasma glucose test**
GPRA	**Government Performance and Results Act**
HBP	**High blood pressure**
HDL-C	**High-density lipoprotein cholesterol**
HRSA	**Health Resources and Services Administration**
HTN	**Hypertension**
IRB	**Institutional Review Board**
JNC 7	***Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7, 2004)**
LDL-C	**Low-density lipoprotein cholesterol**
LSI	**Lifestyle Intervention**
MDE	**Minimum data element**
NBCCEDP	**National Breast and Cervical Cancer Early Detection Program**
NCCDPHP	**National Center for Chronic Disease Prevention and Health Promotion**
NCEP	**National Cholesterol Education Program**
NHLBI	**National Heart, Lung, and Blood Institute**
NIH	**National Institutes of Health**
OGTT	**Oral glucose tolerance test**
OSH	**Office on Smoking and Health**
PA	**Program Announcement**
PHS	**Public Health Service**
PRC	**Prevention Research Center**
RFA	**Request for application**
RTI	**Research Triangle Institute**
SBP	**Systolic blood pressure**
SIP	**Special interest project**
TLC	**Therapeutic lifestyle changes**
WISEWOMAN	**Well-Integrated Screening and Evaluation for Women Across the Nation**

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This document will be made available at the WISEWOMAN Web site.
Visit www.cdc.gov/wisewoman.

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Appendixes

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  - ✧ Physical Activity and Health Branch
- Division for Heart Disease and Stroke Prevention
- Division of Diabetes Translation
- Office on Smoking and Health
- National Breast and Cervical Cancer Early Detection Program

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Overview of the Document

This document was written to provide you and your project staff with the resources and guidance you need to develop, operate, and evaluate a WISEWOMAN project.

The document is organized into five chapters. **Chapter 1** provides background information and the philosophy of the CDC WISEWOMAN program. **Chapter 2** focuses on resources and information needed to administer a WISEWOMAN project. **Chapter 3** provides resources and guidance to establish chronic disease risk factor screening for WISEWOMAN participants. **Chapter 4** contains information to help projects provide a lifestyle intervention that will help participants consume a heart-healthy diet, increase physical activity, and live tobacco-free. **Chapter 5** contains information on program and project evaluation.

Each chapter begins with a brief overview of its contents. Relevant policies are located in boxes throughout each chapter, and an explanation about the policy follows, as needed. A list of all references and sources cited are summarized at the end of the chapters. Additional resources that contain more information on the topic may also be included. The comments in the margin provide you with an explanation for frequently asked questions, point you to another area in the document that contains related information, summarize content, or emphasize a point.

The appendixes contain a list of key terms and their definitions, documents that provide background information or explain why the program has selected a certain course of action, some pertinent publications that you might not have easy access to, and forms that your project can use.

Vision of WISEWOMAN

A world where any woman can access preventive health services and gain the wisdom to improve her health.

Mission of WISEWOMAN

Provide low-income, underinsured, or uninsured 40- to 64-year-old women with the knowledge, skills, and opportunities to improve their diet, physical activity, and other life habits to prevent, delay, or control cardiovascular and other chronic diseases.

Executive Summary

In 1993, Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the WISEWOMAN demonstration program to extend the services provided within the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) framework. This framework provides the opportunity to target other chronic diseases among women, including heart disease, the leading cause of death among women. A subset of the women (those who are 40–64 years of age) who participate in NBCCEDP may also participate in WISEWOMAN. Addressing risk factors such as elevated cholesterol, high blood pressure, obesity, sedentary lifestyle, diabetes, and smoking can help reduce a woman's risk of cardiovascular disease-related illness and death.

The primary purpose of the WISEWOMAN program is to reduce cardiovascular disease and chronic disease risk factors for low-income and uninsured women. In addition, the WISEWOMAN program allows Congress to see whether it is practical to offer additional preventive services through the established NBCCEDP framework. The program also allows the benefits of such services for low-income and uninsured women to be measured. There are two types of WISEWOMAN projects:

Standard projects. The major goal of standard projects is to use effective approaches while conducting the following activities for women aged 40–64 who participated in the NBCCEDP: recruitment; screenings for blood pressure, cholesterol, glucose, weight, smoking, and other conditions (when appropriate); referral; lifestyle intervention (to include promotion of heart-healthy diet, increased physical activity, and tobacco cessation); support and tracking; evaluation; professional and public education; and community engagement.

Enhanced projects. Enhanced projects are designed to determine the most effective lifestyle interventions for underserved women by comparing women who receive an enhanced intervention with women who receive a minimum intervention or usual care. One major goal of enhanced projects is to use scientifically rigorous methods to test the effectiveness and cost-effectiveness of a behavioral or lifestyle intervention that is grounded in the social and cultural context of the priority population and that is aimed at preventing cardiovascular disease. The other major goal is to translate and transfer successful interventions and program strategies to other programs that serve financially disadvantaged women.

As part of the WISEWOMAN program, CDC encourages the existing projects to be creative and flexible in developing models that will be effective in decreasing risk factors for lowering cardiovascular disease and other preventable chronic diseases through nutrition, physical activity, and tobacco cessation interventions. Because projects need maximum flexibility, only those policies needed to effectively administer and meet legislative requirements have been developed. Summaries of these policies follow, but policy details are provided in various chapters of this guidance document. New policies will be developed as needed with input from WISEWOMAN stakeholders and consultants. See Appendix A for the WISEWOMAN policy development framework.

This WISEWOMAN guidance and resource document also provides background information, explanations of legislative requirements, and WISEWOMAN cooperative agreement and program management policies. Appendix B contains definitions of key terms pertinent to the WISEWOMAN program. All WISEWOMAN project staff are encouraged to become familiar with this document. As with any program, this document is a work in progress. As new policies and supporting materials are developed, they will be made available.

WISEWOMAN Policies At A Glance

Chapter 2: Administering Your WISEWOMAN Project

Governing Legislation Policy
Your WISEWOMAN project must follow the legislative requirements detailed in 42 U.S.C. Section 300k of the Public Health Service Act, as amended. NBCCEDP projects also follow these requirements.

Requirement of Matching Funds Policy
For every $3 of federal funds provided by the cooperative agreement, your WISEWOMAN project must contribute $1 in nonfederal contributions, either directly or through public or private donations, as required by Public Law 101-354.

60%/40% Distribution Policy
At least 60% of your project's cooperative agreement funds must be used for screening, health education/lifestyle intervention sessions, diagnostic tests, laboratory fees, tracking, follow-up, and support services to maximize participation in screening and lifestyle intervention sessions. The remaining 40% or less should be used for public education initiatives, professional development, partnerships, community engagement, evaluation and research, and administration as described in 42 U.S.C. Section 300k(a) and 300m(a) of the Public Health Service Act, as amended.

Administrative Expenses Policy
Your project cannot spend more than 10% of federal funds annually for administrative expenses, as noted in 42 U.S.C. Section 300n(f) of the Public Health Service Act, as amended. Administrative expenses are a portion of the 40% component of the budget and are in lieu of indirect costs.

Policy Requiring Two Full-Time Staff Members
Your project must appoint or hire at least two professional staff members to work full-time on WISEWOMAN. One employee shall be a full-time program coordinator, and the other should be an intervention specialist with experience in nutrition, physical activity, or health education. Projects will identify and oversee a WISEWOMAN evaluation team with appropriate experience and training.

Policy on Allowable Diagnostic Tests

WISEWOMAN funds can be used for the following diagnostic tests: fasting lipoprotein panel and fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT).

Policy on A1C Testing

For women with previously diagnosed diabetes, projects may use WISEWOMAN funds to pay for A1C (glycosolated hemoglobin) testing in lieu of a fasting plasma glucose test. This test, as with all other tests conducted at the initial screening visit, will be performed again 1 year (10–14 months) later at the evaluation (first annual) screening visit.

Policy on Evaluation (First Annual) Screening Visit

A system must be in place to track all new WISEWOMAN participants, regardless of screening results, to remind them to return for their evaluation (first annual) screening, which occurs 10–14 months after the initial screening. At least 75% of all new women screened will return for the evaluation screening.

The evaluation screening will consist of the same screening tests that were completed at baseline and will use the same health behavior questions asked during the initial visit. (These are reported as minimum data elements.)

Policy on Medical Referrals for Women with Abnormal Values

A major responsibility of your project staff is to ensure that women with abnormal screening values are referred to a health care provider for appropriate diagnostic examinations in accordance with national and program guidelines. You do not need to submit results from this office visit to CDC, but you will want to periodically review the referral data to detect any problems with your referral system.

Policy on Medical Referral and Documentation for Women with Alert Values

Women with alert screening values must be evaluated and treated immediately or within 1 week, depending on the clinical situation, in accordance with national and program guidelines. For each woman with an alert value, you must document her referral date, diagnostic exam date, and if the medication was prescribed as a minimum data element and submit these data semiannually to Research Triangle Institute.

Chapter 3: Setting Up Your Screening and Referral Services

Policy on Allowable Office Visits

WISEWOMAN funds can be used to reimburse a maximum of two office visits per year for each participant. The content of the office visits will be consistent with the intent of a screening program rather than a treatment program. However, at the discretion of your project, these office visits may be used to provide more in-depth counseling about risk reduction; to reassess whether blood pressure, glucose, or cholesterol goals have been met as a result of completing the lifestyle intervention; to conduct allowable diagnostic testing; or to provide WISEWOMAN screening.

Policy on Allowable Screening Tests

WISEWOMAN funds can be used for the following tests:

- Resting pulse.
- Blood pressure.
- Serum total cholesterol (nonfasting).
- High-density lipoprotein cholesterol (HDL-C) (nonfasting).
- Height and weight measurements.
- Panels that include assessment of blood glucose.
- Urine analysis, including a test for urine cotinine.
- Paper-and-pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

If a woman is fasting during her screening visit, a fasting lipoprotein analysis is allowed and should be conducted to determine cholesterol level, and a fasting plasma glucose is allowed and should be conducted to determine her glucose level.

Policy on Allowable Diagnostic Tests

WISEWOMAN funds can be used for the following diagnostic tests: fasting lipoprotein panel and fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT). The use of program funds for other diagnostic tests will require substantial justification by the project.

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Policy on Case Management
Although WISEWOMAN supports the use of case management to improve adherence to national clinical care guidelines, your project should offer WISEWOMAN-funded case management services only to women with alert values. WISEWOMAN-funded case management services must end when a woman begins receiving prescribed treatment or is no longer eligible for the WISEWOMAN program.

Policy on Access to Medication
Although you cannot use WISEWOMAN funds for treatment, including medication, you must develop a system to ensure access to medications for women who require this augmentation to lifestyle or behavior changes. You should describe this system in your project's protocol.

Policy on Ensuring Adherence to National Guidelines
To ensure that participants receive high-quality care, your project should contract only with health care practitioners who agree to provide care in accordance with national clinical care and prevention guidelines. In addition, your project should offer these practitioners professional development opportunities that promote the use of national guideline recommendations.

Chapter 4: Building a Successful Lifestyle Intervention

Policy on Diabetes-Specific Interventions
Diabetes-specific interventions, to include medical nutrition therapy, will not be reimbursed with WISEWOMAN funds. However, the time spent to identify resources for women with diabetes and to refer these women to diabetes-specific interventions can be supported by WISEWOMAN funds. The WISEWOMAN program recommends that projects identify affordable resources and provide referrals for women with diabetes.

Policy on Lifestyle Intervention Management
You may use WISEWOMAN funds to provide management and support services to promote complete attendance at and adherence to your project's standardized lifestyle intervention program: • Standard projects must ensure that 75% of new women who have completed baseline screening attend at least one lifestyle intervention session and that 60% attend all intervention sessions. • Enhanced projects must ensure that at least 75% of new women who have completed baseline screening in the intervention group complete all lifestyle intervention sessions.

Policy on Tracking Participation in Lifestyle Interventions
Projects will develop a system for analyzing participant data to ensure that a woman enrolled in the lifestyle intervention receives the complete intervention program in a timely manner and to assist with program evaluation.

Chapter 5: Evaluating Your Efforts and Demonstrating That WISEWOMAN Works

Policy on Minimum Data Elements and Cost Da	
Your project should collect and report minimum data elements and cost information in the format suggested by the program to its evaluation contractor (Research Triangle Institute) twice a year:	
Report on April 15	Data collected from program inception through December 31 of the previous year.
Report on October 15	Data collected from program inception through June 30 of the current year.

1 WISEWOMAN's Approach to Improving Public Health

Chapter 1: WISEWOMAN's Approach to Improving Public Health

This chapter should answer many of your questions about the WISEWOMAN program—how we began, our approach to promoting the health of underserved women, and how our services build on the strong foundation already established by CDC's National Breast and Cervical Cancer Early Detection Program.

How and Why Did WISEWOMAN Start?

Heart disease, stroke, cancer, and diabetes account for about two-thirds of all deaths in the United States.[1] Many studies have shown that we can lower people's risk for illness and death from these chronic diseases by reducing risk factors such as high cholesterol, high blood pressure, high blood glucose, obesity, poor diet, sedentary lifestyle, and smoking. However, screening, behavioral interventions, and any necessary treatment services for these risk factors are often beyond the reach of underinsured and uninsured women, who currently account for 14% of U.S. women aged 40–64 years.[2]

To address this unmet need for preventing and detecting heart disease, stroke, and their risk factors among uninsured women, WISEWOMAN (**W**ell-**I**ntegrated **S**creening and **E**valuation for **Wom**en **A**cross the **N**ation) was authorized as a program in 1993 through a legislative supplement to the law that established CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP).[3]

In 1995, CDC launched the first WISEWOMAN demonstration projects in three states: Massachusetts, Arizona, and North Carolina. In 2001, Congress authorized WISEWOMAN to expand to no more than 15 states/tribes.[4] As of 2004, WISEWOMAN reached the cap, with 13 state health departments and 2 tribal organizations receiving funds to provide WISEWOMAN services.

By WISEWOMAN project, we mean each of the 15 state health departments and tribal organizations that make up the CDC WISEWOMAN program. By WISEWOMAN program, we are referring to all 15 projects or the CDC staff in Atlanta.

Congress Has Authorized WISEWOMAN Projects to Conduct These Core Activities

- Projects work with health care providers who offer **preventive health services,*** including screenings for blood pressure and cholesterol and measurement for height and weight, as well as **health education.** In this document, we refer to these services as the lifestyle intervention.
- Projects work with health care providers who make appropriate referrals for medical treatment of women who have abnormal screening results. WISEWOMAN projects, however, are not authorized to use federal funds for treatment, including medication.
- Projects collect data and conduct evaluations to help CDC determine if the WISEWOMAN program is effective and cost-effective.†

* The WISEWOMAN projects also screen women for diabetes and tobacco use.

† In addition, enhanced WISEWOMAN projects are funded to conduct research, using scientifically rigorous methods to test the effectiveness of a behavioral or lifestyle intervention aimed at preventing cardiovascular and other chronic diseases.

What Are the Vision and Mission of the WISEWOMAN Program?

WISEWOMAN's vision is a world where any woman can access preventive health services and gain the wisdom to improve her health.

WISEWOMAN's mission is to provide low-income, underinsured, or uninsured 40- to 64-year-old women with the knowledge, skills, and opportunities to improve their diet, physical activity, and other life habits to prevent, delay, or control cardiovascular and other chronic diseases.

Preventive health services are provided to eligible women through free screening for chronic disease risk factors and structured lifestyle interventions that help participants become more physically active, make healthful food choices, control their weight, and live tobacco-free. Partnerships at the local, state, and national levels are vital to WISEWOMAN's success in carrying out this mission. Thus, CDC works closely with state and tribal health agencies to develop, implement, evaluate, and maintain the WISEWOMAN program.

The authority and funding for adding WISEWOMAN services to the NBCCEDP was given to CDC, an agency known for protecting and improving the public's health. Clearly, WISEWOMAN was intended to be a public health program.

What Does It Mean to Deliver WISEWOMAN Services Using Public Health Principles?

According to senior public health officials, public health should be seen as a crucial population-based practice whose scientific base for defining problems, developing interventions, and measuring results is epidemiology and whose philosophical base for applying scientific knowledge is social justice.[5] These same officials also point out that providing care for low-income individuals often competes with efforts to implement essential or "core" communitywide programs aimed at changing the physical and social environments of these same populations.

Thus, delivering WISEWOMAN using public health principles requires us to not only "link people to needed personal health services and assure the provision of health care when otherwise unavailable" (see services listed below), but to also work with the community to influence the environments of the WISEWOMAN participants. WISEWOMAN should deliver as many essential public health services as possible and affordable.

*Essential Public Health Services**

1. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
2. Monitor health status to identify and solve community health problems.
3. Diagnose and investigate health problems and health hazards in the community.
4. Inform, educate, and empower people about health issues.
5. Mobilize community partnerships and action to solve health problems.
6. Develop policies and plans that support individual and community health efforts.
7. Enforce laws and regulations that protect health and assure safety.
8. Assure a competent workforce—public health and personal care.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
10. Conduct research for new insights and innovative solutions to health problems.

* In 1994, the Essential Public Health Services Work Group of the Core Public Health Functions Steering Committee developed the *Essential Public Health Services* to convey the scope and importance of governmental public health to both the public and legislators. Work group members included representatives from the Association of State and Territorial Health Officials, National Association of County and City Health Officials, Institute of Medicine (National Academy of Sciences), Association of Schools of Public Health, Public Health Foundation, National Association of State Alcohol & Drug Abuse Directors, National Association of State Mental Health Program Directors, and Public Health Service.

To achieve this goal of improving conditions beyond the individual level, WISEWOMAN has requested that projects embrace a framework such as the **social ecologic model** (Figure 1.1), which encourages public health action at the interpersonal, organizational, community, and societal levels as well as at the individual level. WISEWOMAN projects have indeed embraced this model by taking action at multiple levels (Table 1.1).[6]

Figure 1.1. WISEWOMAN Projects Are Encouraged to Take Public Health Action at Many Different Levels

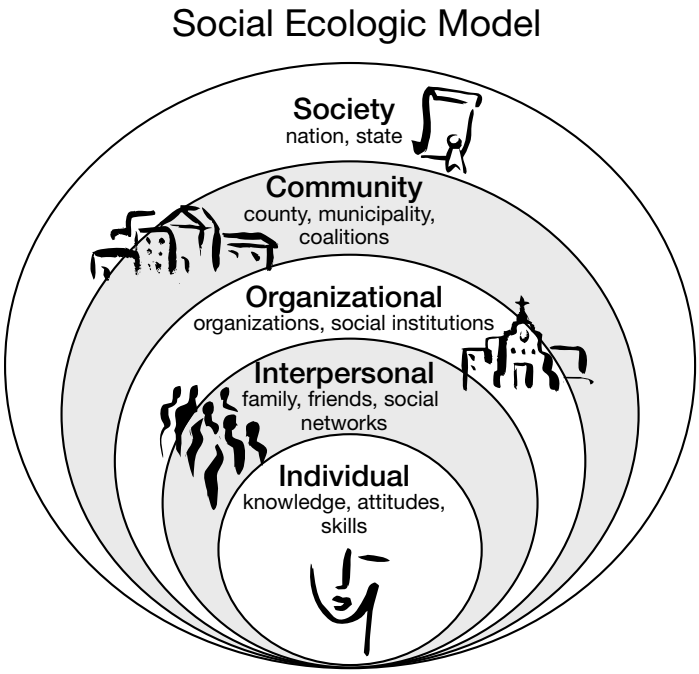


Table 1.1. Examples of WISEWOMAN Activities That Promote Women's Health at Multiple Levels

Social Ecologic Level	Examples of Activities
Individual	Provide screening, diagnosis, referral, case management, medical follow-up, one-on-one lifestyle intervention counseling.
Interpersonal	Offer group lifestyle intervention classes. Develop walking clubs.
Organizational	Extend hours at a clinic to accommodate working women. Encourage providers to follow national clinical guidelines. Implement physical activity prescriptions by providers.
Community	Develop a community garden. Work with community partners to sponsor low-cost walking shoes. Garner community support for providing WISEWOMAN neighborhoods with sidewalks and streetlights. Ask local organizations to provide discounted passes to swimming pools and fitness clubs. Work with local organizations to use their vans or buses to bring women to lifestyle intervention classes. Request that schools keep their gymnasiums open in the evenings and on weekends for community use. Influence the community to address the issues of uninsured community members.
Society	Work with national organizations that offer weight-loss programs, fitness programs, or other health education programs to encourage them to provide discounts for financially disadvantaged populations, including WISEWOMAN participants.

What Are the Key Elements of the WISEWOMAN Program's Approach?

Standard WISEWOMAN projects select interventions that have been rigorously studied and shown to be most efficacious. An efficacious intervention is one that has been shown under ideal conditions to make a statistically significant positive impact on health. Ideal conditions are those in which the methods used allow the investigator to eliminate alternative explanations and conclude with reasonable certainty that the intervention produced the effect. This approach relies on scientific rigor and a highly controlled research environment. A highly controlled study of a lifestyle intervention (also known as an efficacy study) guards against some of the following threats:

- **Events that were not intended to occur** between the baseline and follow-up measurements. For example, a study to assess whether a certain diet can improve cholesterol takes place in a hospital setting where all study participants are fed the same diet. However, a patient's mother sneaks cake into the ward. This event threatens the validity of the study.

- **Changes in the calibration of measuring instruments.** A good example of this is when a machine that tests cholesterol levels is calibrated before the baseline measurement but is never checked again throughout the entire study. Another example is when assessments at baseline and at follow-up are conducted by two different interviewers.

- **Differences in the recruitment of participants into the intervention group and usual care group.** For example, if a study recruited fewer highly motivated people into the intervention group than into the usual care group, one might conclude that a weight loss intervention was not very successful. People in the usual care group might be losing weight on their own, whereas those in the intervention group might not try very hard to lose weight. Randomly assigning participants to intervention and control groups should take care of this problem.

The reality is that WISEWOMAN projects are not conducted under ideal conditions. WISEWOMAN projects are designed to be implemented in the real world, where women eat at home or in fast-food restaurants, where clinics have high staff turnover, and where women may not be highly motivated to participate. Consequently, WISEWOMAN projects are unlikely to see the large changes in risk factors that often are seen in efficacy studies. However, projects such as WISEWOMAN that are

conducted in a real-world setting have some distinct advantages over efficacy studies. One advantage is that WISEWOMAN projects can reach many more women. Whereas efficacy studies typically reach hundreds of women, WISEWOMAN projects will often reach that many women in just a few months and can reach thousands of women over time.

Abrams and colleagues[7] defined the impact of an intervention as the product of its reach and its effectiveness. For example, a highly efficacious intervention conducted in a hospital setting among 200 women that reduced their average systolic blood pressure value by 10 mm Hg would have an estimated impact of 200×10, which equals a 2,000 unit drop in blood pressure. On the other hand, a WISEWOMAN intervention conducted in the real world among 2,500 women that reduced the average systolic blood pressure value by 2 mm Hg would have an estimated impact of 2,500×2, which equals a 5,000 unit drop in blood pressure.

On the basis of these examples, we could conclude that the WISEWOMAN project has had a greater impact than the rigorous, highly effective intervention that was conducted in a hospital setting. Thus, producing small reductions in risk factors among large numbers of women is a reasonable public health approach. Even a small reduction in systolic blood pressure can significantly reduce the number of deaths from stroke and coronary heart disease (Table 1.2).

Table 1.2. In a Population-Based Intervention, Small Declines in Systolic Blood Pressure Reduce Deaths from Stroke and Coronary Heart Disease*

Decline in systolic blood pressure	Leads to →	Decline in stroke deaths	Decline in coronary heart disease deaths	Decline in total deaths
2 mm Hg		6%	4%	3%
3 mm Hg		8%	5%	4%
5 mm Hg		14%	9%	7%

* Source: *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7, 2004).

Another advantage that WISEWOMAN projects have is that they can develop programs that can be easily adopted by others who work with similar populations and in similar settings. This diffusion is a very important part of making a public health impact. In fact, Glasgow and colleagues[8] extend Abrams's concept of impact to include three additional dimensions beyond reach and efficacy: adoption, implementation, and maintenance. The five dimensions of reach (R), efficacy (E),

adoption (A), implementation (I), and maintenance (M) make up the RE-AIM framework (Table 1.3).

In 2004, WISEWOMAN began embracing this framework both for planning programs and for estimating their public health impact. This framework is currently being used in a WISEWOMAN Best Practices study that is looking at those projects that have adequate sample sizes because they have both screened substantial numbers of women and followed them for a 1-year period.

What Are Best Practices?

WISEWOMAN best practices are those project/site activities, practices, or processes within each RE-AIM dimension that are considered most effective for delivering WISEWOMAN services, as indicated by quantitative measures combined with systematically gathered qualitative data. The identification of these effective practices must recognize the widely varying program, policy, cultural, socioeconomic, and geographic contexts in which WISEWOMAN projects operate, as well as their varying stages of development.

For the implementation dimension of the RE-AIM framework, WISEWOMAN projects strive to provide clear protocols, easy-to-use counseling materials, and simple procedures so that clinical staff can easily implement the program in a high-quality and consistent manner. WISEWOMAN incorporates the final piece of this framework—maintenance—by striving to sustain the program and maintain health improvements over time. One of the best ways to maintain behavioral change is to link women to community nutrition, tobacco use cessation, and fitness resources so they can incorporate what they have learned through WISEWOMAN into their daily lives in their own neighborhoods.

Table 1.3. Each of the RE-AIM Dimensions

Dimension	Definition	Level
Reach	Degree to which women participate in the program	Individual
Efficacy/ Effectiveness	Extent that improvements occur in risk factors	Individual
Adoption	Degree to which provider sites, settings, and practices adopt the program	Organization
Implementation	Extent to which the program is delivered as intended	Organization
Maintenance	Extent to which a program is sustained over time Extent to which health improvements are maintained over time	Organization and Individual

In summary, the WISEWOMAN program is committed to a public health approach that strives to

- Deliver the 10 essential public health services.
- Have an impact at multiple levels of society.
- Extend the reach of effective strategies to thousands of women.
- Provide the public health community with model programs that can be easily adopted, implemented, and maintained.

WISEWOMAN and the NBCCEDP: How Are They Alike? How Are They Different?

The WISEWOMAN program and the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) share many similarities, but their focus, services, and age groups served do have some differences (Table 1.4). WISEWOMAN uses the framework already established by NBCCEDP and provides cardiovascular and other chronic disease risk factor screening and lifestyle interventions to a subset of women enrolled in the state and tribal BCCEDP. This framework includes an established infrastructure at the level of the state/tribal health agency that has experience and expertise in

- Recruiting and working with the women eligible for services.
- Delivering screening services through an established health care delivery system.
- Collecting and reporting data (minimum data elements) that are used to track, monitor, and evaluate program efforts.

- Providing professional development opportunities for staff, providers, and partners.
- Promoting the program and providing public education to raise awareness about the need for women to receive program services.
- Assuring that quality care is provided to the women participating in the program.

WISEWOMAN projects build on the state/tribal BCCEDP infrastructure to provide cardiovascular and other chronic disease risk factor screening and lifestyle interventions to women aged 40 and older who are enrolled and remain eligible to participate in the state or tribal organization's BCCEDP. Almost all WISEWOMAN participants are aged 40–64; however, there is an exception. The NBCCEDP allows women over 64 to remain in the program if they cannot afford Medicare, Part B. These women are also eligible for WISEWOMAN services.

Projects are encouraged to provide the participants with the ease and convenience of a one-stop screening visit: one office visit that consists of breast and cervical cancer screening as well as blood pressure, cholesterol, glucose, body mass index, diet, physical activity, and tobacco use screening. The one-stop shopping approach is important for many reasons. Women who qualify for NBCCEDP and WISEWOMAN services often have difficulty getting into the health care system. For example, they might not have a car or access to public transportation. One-stop shopping helps these women access a wider array of vital health screenings that they otherwise might not seek.

One-stop shopping also makes good sense from the provider's perspective, when you consider the time, effort, and money that would be needed to conduct multiple health screenings and interventions during separate visits. Public health dollars are already scarce, and we must do all we can to stretch our resources. This approach can be a model for other health programs that want to offer more comprehensive health services by piggybacking onto an existing program.

One of the major differences between the two programs is the fact that WISEWOMAN provides a lifestyle intervention to promote health. WISEWOMAN projects select or develop a lifestyle intervention that promotes healthy eating, physical activity, and living tobacco-free. Projects also strive to deliver the lifestyle intervention in a way that allows participants to learn and develop new skills in a culturally relevant context.

Table 1.4. Similarities and Differences Between WISEWOMAN and the NBCCEDP

	WISEWOMAN	NBCCEDP
Focus of program	Screening **and** lifestyle intervention program: reducing cardiovascular and other chronic disease risk factors through primary prevention (screening) and health promotion strategies (emphasizing healthful eating, physical activity, and tobacco use cessation).	Screening program: finding breast and cervical cancer as early as possible through testing.
Services provided	Risk factor screening, which must include blood pressure, cholesterol, weight, height, and health behavior assessment. Lifestyle modification interventions to give participants the skills, knowledge, and support they need to eat healthy, be physically active, and live smoke-free. Referrals for women with abnormal values to health care providers for medical management of condition.	Cancer screening: breast exam, Pap test, and mammography. Other services include diagnostic tests to pinpoint problems. Referrals for women with abnormal or suspicious test results to health care providers for medical management of condition.
Year first state/tribal health agency was funded	1995	1990
Age group targeted	40- to 64-year-old women enrolled in NBCCEDP	18- to 64-year-old women (cervical cancer screening) 50- to 64-year-old women (mammography testing)
Rescreening requirement	Emphasis is placed on having at least 75% of the newly screened women return 10–14 months after initial screening for purposes of evaluating impact of program.	Although rescreening women is important, there is not a minimum standard or performance indicator related to this activity.
Number of funded projects	13 state and 2 tribal organizations (Cap of 15 was established by Congress.)	50 states and DC, 4 territories, and 13 tribal organizations
Program administration	Through CDC's Division for Heart Disease and Stroke Prevention,* NCCDPHP†	Through CDC's Division of Cancer Prevention and Control, NCCDPHP†

* From the program's inception until September 2005, the WISEWOMAN program was administered by CDC's Division of Nutrition and Physical Activity.

† National Center for Chronic Disease Prevention and Health Promotion.

References

1. CDC. National Vital Statistics Reports 2003;52(3):8. Hyattsville, MD: National Center for Health Statistics, 2003.

2. CDC. Unpublished analysis conducted with 1999–2002 National Health and Nutrition Examination Survey data. These data are from CDC's National Center for Health Statistics.

3. Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the WISEWOMAN legislative supplement. Available at http://www.cdc.gov/wisewoman/legislation_highlight.htm.

4. Committee Report, House Report 106–1033. Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001. House Resolution 196-1033; 2001.

5. Baker EL, Melton RJ, Strange PV, Fields ML, Koplan JP, Guerra FA, et al. Health reform and the health of the public: forging community health partnerships (special communications). *JAMA* 1994;272(16): 1276–1282.

6. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health Education Quarterly* 1988;15:351–377.

7. Abrams DB, Orleans CT, Niaura RS, Goldstein MG, Prochaska JO, Velicer W. Integrating individual and public health perspectives for treatment of tobacco dependence under managed health care: a combined stepped-care and matching model. *Annals of Behavioral Medicine* 1996;18(4):290–304.

8. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework (abstract). *American Journal of Public Health* 1999;89:1322–1327.

2 Administering Your WISEWOMAN Project

Chapter 2: Administering Your WISEWOMAN Project

This chapter provides you with the information you need to administer a WISEWOMAN project. It is divided into five sections: legislative requirements, other requirements, what the WISEWOMAN program expects from your project, required documents, and what your project can expect from us. Because WISEWOMAN was created out of supplemental legislation that authorizes the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), many of the WISEWOMAN administrative policies are similar to those for NBCCEDP.

Legislative Requirements

The WISEWOMAN program's authorizing legislation and subsequent amendments are critical documents used to development the program announcement and this guidance document. In this section, we will cover the administrative policies and procedures that your project must follow to uphold these legislative requirements.

Governing Legislation Policy

Your WISEWOMAN project must follow the legislative requirements detailed in 42 U.S.C. Section 300k of the Public Health Service Act, as amended. NBCCEDP projects also follow these requirements.[1]

Requirement of Matching Funds Policy

For every $3 of federal funds provided by the cooperative agreement, your WISEWOMAN project must contribute $1 in nonfederal contributions, either directly or through public or private donations, as required by Public Law 101-354.[2]

Your matching funds can be money or in-kind contributions contributed by your organization and partners (including for-profit entities). Generally, if federal monies are allowed for a service or activity, then nonfederal contributions for the same service or activity may be allowed as a source of matching funds for your program. If you are with a tribal

organization, Public Law 93-638 authorizes you to use funds received under the Indian Self-Determination and Education Assistance Act as matching funds.[3]

60%/40% Distribution Policy

At least 60% of your project's cooperative agreement funds must be used for screening, health education/lifestyle intervention sessions, diagnostic tests, laboratory fees, tracking, follow-up, and support services to maximize participation in screening and lifestyle intervention sessions. The remaining 40% or less should be used for public education initiatives, professional development, partnerships, community engagement, evaluation and research, and administration as described in 42 U.S.C. Section 300k(a) and 300m(a) of the Public Health Service Act, as amended.[1]

Staff time should be partitioned according to the activities that your staff members conduct (Table 2.1). Administrative duties belong in the 40% category. One-on-one activities that can be tied to an individual participant (e.g., providing the screening or lifestyle intervention) belong in the 60% category.

Administrative Expenses Policy

Your project cannot spend more than 10% of federal funds annually for administrative expenses, as noted in 42 U.S.C. Section 300n(f) of the Public Health Service Act, as amended.[1] Administrative expenses are a portion of the 40% component of the budget and are in lieu of indirect costs.

The basis for determining the 10% administrative cost is the total amount of federal monies awarded to your WISEWOMAN project. Administrative expenses (i.e., indirect costs) associated with all contracts are considered part of the 10% limitation placed on overall total administrative cost under the cooperative agreement award.

Table 2.1. Framework for Determining 60%/40% Distribution of Cooperative Agreement Funds*

60% of Funds
Screening Services
Allowable office visits (reimbursement of health care provider time or fees for office visits)
Health history and health behavior assessment
Lab costs for screening and diagnostic tests
Lifestyle Intervention
Healthy diet counseling
Physical activity counseling
Tobacco use cessation counseling
Relapse prevention counseling
Maintenance activities
Supporting and Tracking Participants
Translation for participants who do not speak English
Transportation for participants
Coordinating women's participation in lifestyle interventions
Tracking participants to ensure that they complete the lifestyle intervention and return for the evaluation screening
Case management for women with alert values
Incentives to help participants modify health-risk behaviors
Recruitment
Activities to recruit WISEWOMAN participants from within the BCCEDP (sometimes referred to as "inreach" in the NBCCEDP)

40% of Funds
Public Education
Media campaigns and other activities that increase awareness of the WISEWOMAN program
Outreach activities to increase participation in an integrated program (i.e., NBCCEDP and WISEWOMAN)
Educating the public about CVD prevention
Partnerships and Community Engagement
Support and travel to meet with partners
Policy and environmental supports
Activities to increase program sustainability
Professional Development
Conferences and training
Newsletters or updates for providers
Evaluation and Research
Tracking and monitoring data (at both the individual and aggregate levels)
Evaluation of activities to identify opportunities for improvement
Audits to determine quality of care
Focus groups or surveys with providers or participants
Analyzing data, writing publications and reports
All Other Functions
Management and planning
Administrative costs and personnel
Billing
Curriculum and materials development
Reporting requirements such as continuation application, annual report, semiannual submission of minimum data elements and cost data

* Does not apply to nonfederal matching funds.

Other Requirements

Program eligibility. All women aged 40 and older who are enrolled and remain eligible to participate in the state or tribal organization's BCCEDP are eligible to participate in WISEWOMAN.

- Many of the women eligible for WISEWOMAN services represent ethnic and minority populations.
- They have low incomes (250% or less of the federal poverty guidelines).
- They are underinsured or uninsured.
- If they are eligible for Medicare, they are unable to pay the premium to enroll in Medicare, Part B.

Almost all WISEWOMAN participants are aged 40–64; however, there is an exception. The NBCCEDP allows women over 64 to remain in the program if they cannot afford Medicare, Part B. These women are also eligible for WISEWOMAN services.

Reimbursement. Payment for screening services or lifestyle modification counseling may not exceed the amount that would be paid under Medicare, Part B. Each year, your project must provide the WISEWOMAN program with a list of your *Current Procedural Terminology* (CPT) codes and your state's Medicare, Part B rate. See Appendix C for a list of allowable CPT codes.

The WISEWOMAN program also encourages you to ensure that these women do not have to incur any out-of-pocket expenses for participating in WISEWOMAN.

Payer of last resort. Your project cannot use WISEWOMAN funds to pay for any services that are covered by a state compensation program, an insurance policy, a federal or state health benefits program, or an entity that provides health services on a prepaid basis.

Health Insurance Portability and Accountability Act (HIPAA). The HIPAA privacy rule protects the privacy of individually identifiable health information by establishing conditions for its use and disclosure by a health plan, health care clearinghouse, and certain health care providers. However, the WISEWOMAN program is ***not*** a covered entity under HIPAA because it is not a health care provider, health plan, or health care clearinghouse as defined by HIPAA. Rather, WISEWOMAN is a government program whose principal activity is making grants to fund the direct provision of screening and lifestyle interventions.

Your state's Office of General Counsel or equivalent must determine whether your state health/tribal health agency (entities eligible for WISEWOMAN funds) or its subsidiary programs qualify as covered entities. The Centers for Medicare and Medicaid Services is responsible for implementing various provisions of HIPAA (http://www.cms.hhs.gov/hipaa/).[4]

Program materials development and distribution. CDC retains an unrestricted right to use, reproduce, adapt, and disseminate for its own purposes any products that your project develops using WISEWOMAN federal funds. This includes products created by WISEWOMAN cooperative agreement recipients, contractors, subcontractors, vendors, and consultants. These products include, but are not limited to, the following: program curriculum, program participant materials, graphic designs, educational and other informational materials, fact sheets, newsletter templates, and manuals, as noted in DHHS grants regulation at 45CFR Section 74.36.[5]

For your convenience, Program Announcement 03022 *has been included in this document as Appendix D.*

What the WISEWOMAN Program Expects from Your Project

To understand the WISEWOMAN program's expectations, you and your WISEWOMAN project staff should become very familiar with this publication as well as *Program Announcement 03022* (Appendix D). Together, these two documents describe the program's expectations of funded projects. This publication gives a comprehensive view of the WISEWOMAN program's expectations by providing details, recommendations, and examples. In *Program Announcement 03022,* the recipient activities section, starting on page 36, provides a broad view of what WISEWOMAN projects are to accomplish.

Staffing

Policy Requiring Two Full-Time Staff Members

Your project must appoint or hire at least two professional staff members to work full-time on WISEWOMAN. One employee shall be a full-time program coordinator, and the other should be an intervention specialist with experience in nutrition, physical activity, or health education. Projects will identify and oversee a WISEWOMAN evaluation team with appropriate experience and training.

The original proposal that your project submitted should have addressed the requirement to identify and oversee a WISEWOMAN evaluation team of individuals with appropriate experience and training. Projects that are unable to meet this requirement should discuss possible solutions and timelines with their project officer.

Many WISEWOMAN projects share staff with the state/tribal health agency's BCCEDP and other chronic disease prevention programs. For example, the data manager and case manager may work for both the BCCEDP and WISEWOMAN program, and the epidemiologist and evaluator may also work for the state's chronic disease section. WISEWOMAN supports the use of sharing relevant staff because of the crosscutting nature of the program. However, because of the complexities of the WISEWOMAN program, you must meet the minimum staffing requirement policy.

Projects that have difficulty hiring staff must develop a plan to contract out or identify alternative methods for meeting this requirement. During the interim period, before the full-time staff has been hired, the staffing plan should indicate who will complete each of the major responsibilities listed below.

Full-time WISEWOMAN project coordinator. Responsibilities may include but are not limited to the following:

- Manage or oversee the planning, development, implementation, and evaluation of a program that accomplishes the recipient activities of the WISEWOMAN program listed in Component 3 of *Program Announcement 03022.*
- Oversee all WISEWOMAN activities/components: cardiovascular and other chronic disease risk factor screening, lifestyle intervention, tracking and support of participants, public education, community engagement, professional development, evaluation, and administration.
- Ensure that women receive cardiovascular and other chronic disease risk factor screening and return for the evaluation screening in accordance with program guidance.
- Oversee all management, planning, and staffing issues for the WISEWOMAN program. Ensure that reports and minimum data

elements (MDEs) and cost data submissions are timely, complete, and accurate.

- Communicate the program's goals, objectives, policies, and requirements to partners through methods that best meet the needs of busy health care providers and health educators/intervention specialists. Develop a way to provide feedback about accomplishments.
- Develop strategies that help screening providers and lifestyle interventionists reach women from diverse populations. One such strategy is to ensure that curriculum, brochures, recommendations or counseling, marketing, and media campaigns are culturally appropriate.
- Ensure that systems are in place to achieve program performance standards and reporting requirements.
- Work with partners and engage the community to identify methods that help women maintain behavioral change.
- Work with partners and engage the community to identify methods to sustain the program in future years.
- Use a team approach to evaluate the effectiveness of the program activities. Ensure that the evaluation activities are developed and carried through.
- Develop protocols in accordance with those listed later in this chapter. Protocols should be written in a way that makes it easy for providers to implement and adopt WISEWOMAN strategies. The coordinator is responsible for reviewing protocols at least once a year, making appropriate changes, and ensuring that the CDC project officer approves all protocols.
- Pilot test new strategies and make appropriate changes to protocol, as needed. One goal is to maximize the number of providers willing to offer WISEWOMAN to their eligible clients and thus maximize the reach of the program.
- Create and implement a training plan to ensure that providers and lifestyle interventionists follow program guidance.
- Work collaboratively with CDC, other funded WISEWOMAN programs, and other CDC-funded programs.

Full-time WISEWOMAN intervention specialist. Responsibilities may include but are not limited to the following:

- Plan, develop, implement, and manage the lifestyle intervention component of the program.
- Work with a planning committee to select or develop the lifestyle modification intervention (standard projects are to select an evidence-based lifestyle intervention, whereas enhanced projects may develop the lifestyle intervention they plan to test). The planning committee's internal partners should include representatives from other state programs such as chronic disease, nutrition, health promotion and disease prevention, diabetes, cardiovascular health, office of minority health, office of women's health, 5 A Day, physical activity, and tobacco control. A representative from the target population and health care community should also be a part of the planning committee.
- Develop and use a variety of educational methods and materials.
- Identify incentives that will help participants adopt or maintain their behavior change.
- Identify and work with programs within your organization that have compatible behavior-change goals and messages.
- Identify or develop simple key messages that your project will promote throughout the lifestyle interventions. For example, these messages could be related to eating more fruits and vegetables, eating more whole grains, eating less saturated fat, or walking at least 30 minutes per day.
- Ensure that each lifestyle intervention's key components are conveyed as designed.
- Identify key components of the lifestyle intervention: strategies that are core to helping women receive the knowledge and skills they need to improve their diet, increase their physical activity levels, and live tobacco-free.
- Develop methods to ensure that women complete all the lifestyle intervention sessions.
- Evaluate the lifestyle intervention messages and components to determine if they are effective at helping women achieve behavioral goals.

- Conduct focus groups with local interventionists and participants to identify strategies that will strengthen the lifestyle intervention and participation.
- Train lifestyle interventionists on all aspects of the intervention.
- Ensure that all program components and materials (e.g., curriculum, brochures, recommendations and counseling, marketing, media campaigns) are culturally appropriate and use plain language.
- Identify partners and engage the community to develop methods and resources that help women sustain or maintain behavior change.
- Identify high-quality, low-cost resources that support behavior change, and encourage lifestyle interventionists to help women take advantage of resources available in their community.
- Develop a tracking or data management system that meets the program's reporting requirements.

Policy Requiring Staff Travel to Annual Meetings

At a minimum, your project staff must travel to the following CDC-sponsored meetings each year:

- *Annual WISEWOMAN meetings:* At least two staff members (one of whom shall be the full-time project coordinator) must attend the mandatory WISEWOMAN meeting (place and time to be determined each year).
- *Data managers' meeting:* At least two staff members must attend the mandatory data managers' meeting (place and time to be determined each year).
- *Nutrition and Public Health Course:* One staff member (program coordinator, director, health educator, or designee) must attend this mandatory course (place and time to be determined each year). If all key WISEWOMAN staff members have attended this course, then funds may be used to send a person to another CDC-sponsored course. For example, the Physical Activity and Public Health Course or the annual 5 A Day meeting.

Building Capacity Through Staff Development

WISEWOMAN project staff. Preventing and controlling cardiovascular and other chronic diseases requires that project staff understand

- Methods for detecting chronic diseases.
- Methods for implementing effective lifestyle interventions to reduce risk factors for cardiovascular and other chronic diseases in vulnerable populations.
- Systems that provide good-quality health care for underserved women.
- Methods for assessing whether programs are effective.

Some state/tribal health agencies will already have staff members who possess these skills and knowledge. However, projects in areas without such resources may need to either recruit new staff or train existing staff to attain this expertise.

The WISEWOMAN program recognizes the importance of training staff to carry out these activities and build your project's capacity. WISEWOMAN supports the use of funds for training local staff to implement WISEWOMAN methods according to national, program, and project standards.

Policy Requiring Training Plans

To support capacity building, your project is required to develop an annual training plan that describes what that year's training topics and objectives are, who will attend the training, and how often the training will be offered. You should give a high priority to training staff members, contractors, and volunteers on how to meet the program's performance and reporting requirements. You are required to update your training plan annually and submit it with your interim progress report.

Your training plan will be driven by the protocols your project has developed. For example, you will need to incorporate into your training plan all of the screening standards and the lifestyle intervention activities described in your project's protocols.

Training Recommendations Based on Lessons Learned

The three original WISEWOMAN programs learned many valuable lessons during the program's early years:

- If you decide to train project staff at their facility, this will be very effective, but labor-intensive.
- If on-site training is not feasible, your next best option may be to train staff from several programs in the same region.
- With any method of training (e.g., face to face, videoconferencing), make sure that the staff members who are most involved with the project attend the training.
- Use a comprehensive training manual, small-group discussions, role-plays, demonstrations, discussions of counseling strategies and social support mechanisms, and other techniques suited to adult learners.
- To enhance learning, make the training as interactive and hands-on as possible.
- Offer your staff frequent opportunities for refresher training.

Sustaining the Program

To ensure that your screening and lifestyle interventions help underserved women for many years to come, your project must make the most of WISEWOMAN's crosscutting benefits. Because good nutrition, physical activity, and tobacco use cessation are key to preventing and managing so many chronic diseases, your WISEWOMAN project can be a catalyst for promoting health at the state and local levels. To capitalize on the unique nature of WISEWOMAN, you should work with traditional and nontraditional partners in the community as well as other CDC-funded programs to leverage resources and identify ways of sustaining the program in future years.

Working closely with the community and other partners is essential to your project's success in future years. For guidance, advice, and helpful examples of how to collaborate with partners, refer to CDC's *Principles of Community Engagement* (http://www.cdc.gov/phppo/pce/index.htm).[6]

Another strategy to sustain your project is to make sure that WISEWOMAN activities become a part of your state's or organization's official strategic planning document, often referred to as the "state plan."

You can also foster collaborations that could lead to sustainability by thinking strategically about how to meet WISEWOMAN's matching funds requirement. The following list of match ideas were generated by currently funded WISEWOMAN projects and may be used as a springboard to generate additional ideas:

- The American Heart Association or another nongovernmental organization (NGO) may provide your WISEWOMAN project with public education, materials, literature, mailings, staff time, and professional education specific to women and heart disease and with a special focus on minority women. Contributions can range from a few dollars to many thousands of dollars.
- Advisory committee members can contribute their time as in-kind contributions to your WISEWOMAN project.
- Local providers or agencies could be required to provide matching funds.
- A state association of health plans can donate pedometers or other supplies to WISEWOMAN participants attending a conference.
- Media outlets can donate time for public education.
- The local YMCA, YWCA, community pools, or other organizations that promote physical activity may provide free or reduced-cost membership or passes to WISEWOMAN participants.

Required Documentation

Your project must provide accurate and complete documentation throughout the lifespan of the cooperative agreement. Some of the major requirements that will be discussed in this section are as follows:

- Submit **protocols** to your project officer for review and approval—this must be done before you can provide screening or the lifestyle intervention to any participant.

- Submit **progress reports** and **financial status reports** to CDC's Procurement and Grants Office (PGO), where they become part of the project's official file.
- Send **budget requests** to PGO to be reviewed and approved prior to the release of funds.
- Send any **request for prior approval** to PGO. Your project staff must become familiar with all the activities that require prior approval.
- Submit **MDE** and **cost data** semiannually.

To assist you with meeting these documentation requirements, please refer to the "additional resources" section at the end of this chapter.

Checklists for Newly Funded Projects

If you have a standard or enhanced project that is funded at the first funding level, you must complete the WISEWOMAN program start-up checklist before you can move to the second funding level, as noted in *Program Announcement 03022* (see Appendix D, page D-80). This checklist (see Appendix E) was adapted from a checklist created for the North Carolina WISEWOMAN project, which is provided in its WISEWOMAN manual, *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program.*[7] The manual was developed by the Center for Health Promotion and Disease Prevention at the University of North Carolina at Chapel Hill as a how-to guide for developing an integrated cardiovascular disease screening, lifestyle intervention, and evaluation program for low-income and/or uninsured women. Your project officer will review the WISEWOMAN Orientation for New Project Staff, which includes an orientation checklist (see Appendix F).

In addition to these checklists, we have created a comprehensive list of protocol elements to help CDC project officers determine when your project is ready to begin screening and lifestyle intervention activities and to assess how thoroughly your activities are planned and carried out.

Protocols

Protocol Requirements

Your project must develop detailed protocols that describe how you will address key elements of the screening and lifestyle intervention services and how you plan to raise awareness about, sustain, and monitor key WISEWOMAN activities. Your CDC project officer must approve all protocols before your project begins screening or lifestyle intervention activities. In addition, if your project is an enhanced project (i.e., funded to conduct research), you will need to work with your CDC project officer to determine what procedure will be needed for Institutional Review Board (IRB) approval.

What Are Protocols?

WISEWOMAN protocols provide a road map or orientation for all employees and contract providers. Some projects may refer to these documents as their standard operating procedures. Development of and adherence to protocols by staff are crucial to the integrity of the program.

WISEWOMAN protocols provide a road map or orientation for all employees and contract providers. Some projects may refer to these documents as their standard operating procedures. Development of and adherence to protocols by staff are crucial to the integrity of the program. All protocols should incorporate national guidelines, as appropriate.

Projects should involve health care providers, supervisors, community health workers, interventionists, and even participants, as appropriate, in protocol development. Development involving key stakeholders will not only result in the creation of relevant protocols, but also may gain buy-in or support of protocols at multiple levels. Plans are needed to assure that all WISEWOMAN staff and providers review protocols and receive appropriate training to increase adherence to protocols.

WISEWOMAN anticipates that protocols will continually evolve as the program is refined through feedback and evaluation. Project and CDC staff should review protocols at least once a year.

Screening Protocol

You must address the following elements in your screening protocol:

- **Training and national guidelines.** Ensure that staff members have training specific to their responsibilities, access to consultation from appropriate health professionals, and adequate supervision. Describe how providers will follow national screening guidelines. Describe how projects will monitor providers' adherence to guidelines (e.g., projects will check to ensure that providers are recording at least two blood pressure measurements for each woman).
- **Integration with BCCEDP screening visit.** Describe how the cardiovascular and other chronic disease risk factor screening will be incorporated with the woman's breast and cervical cancer screening appointment. If the screenings are not integrated, describe strategies that will be used to decrease the burden on the participant due to having two screening appointments.
- **Laboratory standards.** Adhere to all applicable requirements established under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Ensure precise and accurate cholesterol and blood glucose measurements.
- **Oral and printed communication of screening results.** Describe how interpretation of test results will be reliably communicated to the participant orally and in writing.
- **Screening site selection.** Describe how sites are selected for WISEWOMAN screening. Indicate if or when the project plans to provide WISEWOMAN services statewide. WISEWOMAN recommends utilizing "strong" BCCEDP sites for pilot sites: those that can offer comprehensive services, are convenient, serve an adequate number of women (including women representing minority groups), incorporate quality control procedures, and ensure privacy. At a minimum, the percentage of minority women served by WISEWOMAN should reflect the percentage of minority women served through BCCEDP.
- **Formalized commitments.** Describe methods used to assure that all WISEWOMAN program protocols are followed, including letters of cooperation or other formal agreements. Please provide a sample of the agreement when the protocol is submitted to CDC.
- **Screening costs.** Describe which screening tests will be performed and the reimbursement rates for each test or procedure. Submit a current list of CPT codes that the project intends to use. The schedule of fees and charges should not exceed the maximum allowable charges established by the Medicare Program administered by the Center for Medicare and Medicaid Services (see http://www.cms.hhs.gov/).[8] WISEWOMAN strongly encourages projects to use WISEWOMAN funds to pay 100% of the Medicare-allowable charge (i.e., WISEWOMAN clients should not have any out-of-pocket expenses). For a list of allowable CPT codes, see Appendix C.
- **Referrals and medical follow-up.** Describe the screening agency's clinical referral and medical follow-up system to ensure that women with abnormal results obtain medical care in accordance with national guidelines. Describe how your project will determine if timely and appropriate care for women with abnormal non-alert screening values occurs.

- **Support services.** Describe the type of support services offered to WISEWOMAN participants to increase the number of women who complete the baseline and evaluation (first annual) screening visit. These may include incentives, transportation, translation, and childcare services.
- **Evaluation (first annual) screening.** Describe how women will be reminded about their evaluation screening visit. This screening occurs 12 months (+/- 2 months) after the initial screening. The same screening tests and behavior or health-risk appraisal questions conducted at the initial screening visit are repeated at each annual screening visit. There is a performance indicator related to the evaluation screening visit.
- **Annual (beyond the evaluation or first annual) screening.** Projects will need to determine and describe the level of effort they will use to have women return for screening beyond the evaluation screening. There is not a performance indicator related to the annual (beyond evaluation) screening visit. However, the project still needs to report the results and meet MDE requirements if WISEWOMAN funds pay for this visit.
- **Access to medication.** Describe how the project will assure that providers will assist participants who need medication, including providing access to any sliding-scale fees, discounted drug programs, or available indigent drug program.
- **Tracking and monitoring.** Describe the tracking system that will be used to ensure that women will return for their evaluation (first annual) rescreen and subsequent annual screening appointments so that complete and accurate data are collected.
- **Case management for women who have alert values.** Describe the system for referral and care of women with alert values. Case management should be made available to women with alert values. Include a description of procedures for notifying the participant of her alert value.
- **Consent form.** Develop a consent form that meets program requirements and/or Institutional Review Board (IRB) clearance. See Appendix G for the elements needed in a consent form appropriate for standard projects. Enhanced projects should refer to CDC's Web site for Human Subject Research, which contains information about consent forms, at http://www.cdc.gov/od/ads/hsr2.htm.
- **Promote lifestyle intervention.** Describe if intervention data, such as attendance and topics covered, will be shared with the screening provider. Describe how the screening agency will encourage women to participate in lifestyle intervention activities.
- **Adverse event report.** Enhanced projects will describe the proposed system for reporting adverse events from the clinic to the state/agency and from the state/agency to CDC.
- **Data reporting system.** Describe the system for data collection and reporting of MDEs obtained during the screening visit (to include medical history, screening results, and health behavior questions) and submit samples of developed forms.

Lifestyle Intervention Protocol

You must address the following elements in your lifestyle intervention protocol:

- **Lifestyle intervention selection.** Describe and provide rationale for the selected intervention. Describe the theoretical foundation that was used to guide the development of the intervention. Describe the primary goals of the intervention (e.g., increase fruit and vegetable intake, increase number of steps taken each day). Provide the CDC project officer with reference citations, if available.
- **Lifestyle intervention strategies that support national guidelines.** Describe the type of tobacco use cessation, nutrition, and physical activity strategies that will be used in the intervention (e.g., incorporating therapeutic lifestyle changes as described in the Adult Treatment Panel III report,[9] promoting the DASH eating plan as described in the Seventh Report of the Joint National Committee[10]). Strategies should be based on national guideline recommendations, and the project should provide evidence of its success with a population similar to the WISEWOMAN population (i.e., low-income women, middle-aged women, and women representing minority/ethnic groups).
- **Lifestyle intervention counseling.** Describe who will provide the lifestyle intervention, where the intervention will occur, and how often it will be provided. That is, will the counseling be one-on-one or in a group setting, face-to-face or over the telephone, at the screening provider's site or out in the community, provided by a nutritionist/health educator or community health worker, and so forth? Include a description of the topics covered during each session, the length of the session, and how behavioral assessments and individualized goal setting will occur.
- **Data reporting system.** Describe the system for collecting and reporting MDEs about the lifestyle intervention visits (e.g., number and type of sessions attended). Include a sample of forms developed. This information will be used to determine the exposure to the intervention and whether completion of the lifestyle intervention activities was timely.
- **Lifestyle intervention process measures.** Describe the system for determining if the intervention is provided as intended. For example, will the interventionist complete a checklist indicating what was covered at each session with the participant? Will someone from the health/tribal health agency conduct periodic observations of the intervention?
- **Intervention management.** Describe all coordination efforts that are available to maximize intervention attendance. Include plans for overcoming barriers that prevent women from participating in lifestyle intervention activities.
- **Behavior change maintenance.** Describe efforts that will be used to assist women with maintaining behavior change. This may include targeted mailings; follow-up telephone calls; referring women to community organizations that promote healthy eating, physical activity, and/or tobacco-free lifestyles; and working with community partners to provide low-cost or free access to activities.

Protocol to Raise Awareness of, Sustain, and Monitor the Project

You must address the following elements in your protocol describing how you will raise awareness of and interest in the WISEWOMAN services, sustain the project, and monitor it:

- **Recruitment (using strategies to reach women within and outside of the BCCEDP).** Determine who will conduct the recruiting for WISEWOMAN services and how this recruitment will occur. Describe recruitment training efforts and strategies that maximize the number of 40- to 64-year-old women enrolled in BCCEDP to participate in WISEWOMAN screening and lifestyle intervention services. Describe procedures that notify the provider when a woman is eligible for WISEWOMAN services. Outreach recruitment strategies should only be used if WISEWOMAN and BCCEDP are completely integrated to avoid providing WISEWOMAN services to women who are not enrolled in BCCEDP.
- **Public health advisory committee.** This committee consists of experts who form an interdisciplinary team to provide advice on the direction of your project as well as specific project issues. Describe who is on this committee (e.g., physicians, public health practitioners, nutritionists, interventionists, evaluation staff, participants), including their title or experience, how often the committee will meet, and the activities for which they will be convened to advise upon. Recommendations for involving the public health advisory committee are noted throughout this guidance document.
- **Integration of staff.** Describe how staff from the different chronic disease programs in the agency will work together to promote WISEWOMAN (and vice versa). Describe efforts for cross-training and job sharing.
- **Public education.** Describe the public education activities that will be designed to deliver a clear, consistent message about the need for heart disease, stroke, and other chronic disease screening and lifestyle interventions. Describe how the campaign will reach WISEWOMAN priority populations and encourage participation in WISEWOMAN activities.
- **Training plan.** Provide an annual training plan for staff members, contractors, and volunteers with a focus on meeting the program's performance and reporting requirements. This plan should include training topics, training objectives, training participants, and training schedule.
- **Collaboration to sustain the project.** Describe all collaborative efforts. Include a list of key state- and local-level partners, the frequency of meeting, a plan for supplementing existing services, and a plan for raising awareness in the community about WISEWOMAN screening and lifestyle intervention activities. Collaborative efforts will increase the likelihood of the project's sustainability.

- **Partnerships to leverage resources.** Describe relationships with traditional and nontraditional partners, including the state's Primary Care Association, American Heart Association, pharmaceutical organizations, state universities, and prevention research centers. In addition, describe the relationship the project has with state nutritionists, 5 A Day coordinators, physical activity interventionists, community health workers, chronic disease prevention programs (e.g., breast and cervical cancer screening program, cardiovascular disease, diabetes prevention program, tobacco control), and offices of women's and minority health.
- **Community support.** Describe partnerships at state and local levels, including community networks, partnering with local community health organizations, and grassroots efforts to increase awareness of heart disease and stroke risk factors in women and extend services to reduce these risk factors.
- **Quality assurance.** Describe monitoring activities included in the quality assurance plan. The purpose of the quality assurance plan is to ensure high standards of services delivered through the WISEWOMAN program. CLIA standards and national clinical care guidelines should be used to develop the quality assurance plan.
- **Evaluation plan.** The evaluation plan is to include clearly stated evaluation objectives with a timeline for the collection of data throughout the project period. The project can link evaluation objectives to data collected for MDEs and other data sources that are collected by the program. At least one key objective or activity per goal should be monitored and evaluated to determine quality, success, and/or effectiveness. The template to be used for creating the evaluation plan may be found in Appendix H and at http://wisewoman.forum.cdc.gov.[11]

Furthermore, enhanced projects are required to submit an evaluation plan that examines the impact of their lifestyle intervention on lowering WISEWOMAN participants' blood pressure, lowering total cholesterol levels, raising high-density lipoprotein cholesterol levels, and improving other risk factors such as poor nutrition and inadequate physical activity. The impact should be measured soon after completion of the lifestyle intervention (about 6 months after baseline) and again at 12 months after baseline. For details about the evaluation plan for enhanced projects, refer to *Program Announcement 03022* (see Appendix D, page D-43).

Updating Protocols Each Year

Each year, you should submit updated protocols to your project officer. Be sure to include samples of all developed or draft data collection forms and other materials when you submit the protocols.

Progress Reports

In accordance with *Program Announcement 03022,* you must submit a number of reports to PGO each year (deadlines for key reporting activities are listed in Table 2.2).

Interim Progress Report

The **interim progress report** is due the 15th of February each year of the project period (now through 2008). The interim progress report will serve as the project's noncompeting continuation application and must include the following elements:

a. A succinct description of the program accomplishments/narrative and progress made in meeting each of the current budget period activities and objectives during the first 6 months of the budget period (June 30 through December 31).

b. The reason(s) for not meeting established program objectives and strategies to be implemented to achieve unmet objectives.

c. Financial progress report for the current budget period.

d. New Budget Period Proposed Activities and Objectives (commonly referred to as the work plan). A sample work plan is in Appendix H, and a downloadable version is available at http://wisewoman.forum.cdc.gov.[11] WISEWOMAN also asks projects to describe and submit annual training and evaluation plans. These can be incorporated into the annual work plan (see Appendix H).

e. Detailed Line-Item Budget and Justification. A sample budget is in Appendix J, and a downloadable version is available at http://wisewoman.forum.cdc.gov.[11]

f. For all proposed contracts, provide the following six elements:

   1. Name of contractor.

   2. Method of selection.

   3. Period of performance.

   4. Scope of work.

   5. Method of accountability.

   6. Itemized budget with justification for each line item.

If the above contract information is not available, please indicate "To Be Determined" until the information becomes available; it should then be submitted to the PGO contact identified in the program announcement.

Annual Progress Report

The **annual progress report** is due 90 days after the end of the budget period (29th of September). This report should address elements a–c listed above for the interim progress report for the entire 12-month budget period.

Also due at this time is the financial status report (FSR), which is used to officially report any unobligated funds to CDC. An FSR is required for each budget period and the final project period. Ninety days after the end of each budget period, an FSR is due to PGO. However, you may make adjustments up to 15 months after the end of the budget period. You should submit documentation of your current year's estimated unobligated dollars on your SF 424A (Standard Form 424A, Budget Information—Non-Construction Programs), which you will submit with the continuation application.

Prior Approval Requirements

Once your project has been awarded funds, you must obtain written prior approval from PGO for the changes listed below. Failure to obtain prior approval might result in the disallowance of funds. For additional information on prior approval requirements, see the PHS Grants Policy Statement ("the yellow book" at http://grants.nih.gov/grants/policy/gps).[12] The following changes are some of the more common or relevant items that need prior approval:

- Change in project coordinator/director, principal investigator, or other key staff, or the absence thereof for more than 3 months.
- Change in project scope or objectives, regardless of whether the budget is affected.
- Transferring substantive programmatic work by contracting or any other means to a third party.
- Carryover of unobligated funds from one budget period to another within an approved project period.
- Extensions of the budget/project period with or without additional funds.
- Rebudgeting or redirecting a cumulative amount of funds for the current budget period that exceeds 25% of the total amount awarded, or $250,000, whichever is less.
- Redirection of funds that were intended for training costs.
- Publication and printing costs exceeding $25,000 for a single publication when not included in the originally approved budget.
- Equipment purchases exceeding $25,000.
- Requests for additional federal funds.

For additional information on the documents required by PGO, see the links listed in "Additional Resources" at the end of this chapter.

Checklist for All Requests Sent to PGO

Use this checklist to increase the likelihood of having your request approved the first time you submit it to your PGO grants management specialist.

☐ Review the request with your project officer before submitting it to PGO.

☐ Give your project officer a courtesy copy of all correspondence with PGO. This can be an electronic or hard copy.

☐ Make sure your correspondence to PGO includes the items listed below. The PGO staff has said this list represents the most common items left off of correspondence that can cause a delay in response/approval:

1. A cover letter with two signatures (the signature of the principal investigator and the signature of the business office official).
2. A budgetary request for a contractor that includes the six elements for each proposed contract (see page 33, item f).
3. A budgetary request that includes match information (source of match, amount of match, type of match, method of establishing value of noncash match, and method of documenting actual match received).
4. Your project's **cooperative agreement number on all PGO correspondence.**

Minimum Data Elements and Cost Data

Minimum data elements (MDEs) are a set of standardized data elements developed to ensure that consistent and complete information on screening location, participant demographic characteristics, screening results, and lifestyle intervention sessions are collected on participants in the WISEWOMAN program. Cost data are requested from projects and are reported at the same time as the MDEs. Your project can use MDEs and cost data to determine if your WISEWOMAN activities are effective and cost-effective. The MDEs are collected for each woman, computerized, converted into a standardized format, and transmitted to our data contractor, Research Triangle Institute (RTI).

The project summary report was created to be a management tool for WISEWOMAN project staff. The report is generated semiannually for each individual project and for all projects in aggregate using the MDEs. The project summary report includes the program's standards for performance indicators. It provides management with an at-a-glance view of how the project is progressing over time and can be used to make data-informed decisions. We encourage you to share some or all of your report with your public health advisory committee, screening providers, lifestyle interventionists, and other stakeholders.

Reports, user's guides, and documents related to MDEs and cost data may be accessed electronically at https://wisewoman.rti.org/.[13] See Appendix J for a sample project summary report using the aggregate data format.

Table 2.2. Deadlines for Key Reporting Activities

Due Date	Information to Be Sent
February 15	Interim progress report sent to PGO.*
April 15	Minimum data elements and cost data sent to Research Triangle Institute (RTI), the program's evaluation contractor. (Data collected from program inception through December 31.)
September 29	Annual progress report sent to PGO.*
September 29	Financial status report (FSR) sent to PGO.*
October 15	Minimum data elements and cost data sent to RTI. (Data collected from program inception through June 30.)

* Please provide your CDC project officer with a courtesy copy of these reports and any other documents you submit to PGO.

What Your Project Can Expect from Us

The program announcements list activities that CDC will provide to funded projects. The technical assistance that your project officer provides is based on WISEWOMAN's vision, mission, goals and objectives, and, of course, your project and the CDC activities listed in the program announcement. The following list describes some of the activities that CDC WISEWOMAN project officers are responsible for providing to projects:

Technical Assistance and Consultation

- Provide consultation and technical assistance to recipients concerning programmatic or technical matters, as requested.

- Identify potential or existing problems or issues affecting the project and share with appropriate staff information and/or findings concerning those problems. Participate with other staff, as appropriate, in resolving those problems or recommending actions for resolving the problems.
- Identify innovative programmatic or administrative strategies to address complex technical assistance needs.
- Provide clear explanations of CDC policies and procedures, current program activities, and future directions.
- Serve as a resource to identify alternative sources of information from other programs at or funded by CDC, other federal agencies, or national and professional organizations.

Cooperative Agreement Management

- Evaluate all projects for programmatic performance, progress, and any changes using information gathered from site visits, progress reports and other reports, correspondence, and other sources.
- Review reports submitted by your project and ensure that they meet HHS requirements. When the review has been completed, the project officer notifies the grants management officer (in PGO) in writing regarding the satisfactory or unsatisfactory progress of the recipient. That documentation must be included in the official (PGO) grant file.
- Provide input to grants management staff on correspondence from recipients on business management issues.
- Help projects identify and provide all required information for removing programmatic or budgetary restrictions.
- Help projects ensure that program expenditures are in accordance with Public Law 101-354 and its amendments, regulations, and programmatic and budgetary policies.
- Facilitate communication with PGO for timely response to a project's requests for budgetary actions.

Below is the list of CDC activities included in *Program Announcement 03022.* The bulleted items have been added to provide greater detail or additional explanation of the CDC staff and/or the WISEWOMAN project officer's responsibilities.

CDC Activities[14]

a. Convene workshops, trainings, and/or teleconferences among the funded projects for sharing information and solving problems of mutual concern.

- CDC will convene workshops or trainings such as the Nutrition and Public Health Course on an annual basis.
- CDC will convene an annual WISEWOMAN meeting.
- CDC will convene an annual data manager's meeting.
- CDC will convene bimonthly teleconference calls with all funded WISEWOMAN projects.
- CDC will work with representatives from all of the WISEWOMAN projects to plan future activities and to solve problems, as needed.

b. Provide ongoing consultation and technical assistance to plan, implement, and evaluate program activities.

- CDC project officer will contact projects on a regular basis (at least monthly) via telephone to provide guidance with protocol development and to review the work plan, interim and annual progress reports, and budget.
- CDC and contractor will review MDE submission and project reports and assist with development of appropriate follow-up action plans.
- CDC project officer will respond to voice or e-mail requests within 48 hours to acknowledge receipt of request. At that time, the project officer will communicate how the request will be addressed and provide the project with a status update, as needed. If the project officer is out of the office for a length of time greater than 48 hours, an alternative contact will be identified.

c. Conduct site visits to assess program progress and mutually resolve problems, as needed, or coordinate reverse site visits to CDC in Atlanta, Georgia.

- CDC project officer will conduct site visits on a regular basis (minimum of one site visit per year) or as warranted to provide technical assistance and monitor project progress.
- Reverse site visits to Atlanta may be coordinated. In addition, a meeting may be arranged during the annual WISEWOMAN meeting.

d. Assist in the development of a research study protocol for IRB review by all cooperating institutions participating in the research project. If CDC IRB review is necessary, the CDC IRB will review and approve the protocol initially and at least once a year thereafter until the research project is completed. For more detailed information on the CDC IRB, see http://www.cdc.gov/od/ads/hsr2.htm.[15]

   The CDC project officer or other CDC staff may

   - Assist with protocol development.
   - Participate in planning the study.
   - Participate in planning meetings.
   - Serve on steering committees and working groups.
   - Submit material such as questions and questionnaires for consideration.
   - Review study materials, including protocols and study manuals.
   - Analyze data without identifiers (i.e., data that do not contain information that could reveal an individual participant's identity).
   - Serve as author or coauthor on manuscripts for publication.
   - Facilitate discussion between the university partner and health department of the state, territory, or tribal organization.

e. Collaborate with WISEWOMAN projects in the analysis of data and development of abstracts and publications that inform the program, public, scientific community, and Congress about program progress and results.

f. Copy and distribute materials developed by state, territorial, or tribal WISEWOMAN projects for the purpose of aiding other WISEWOMAN projects and public health partners.

References

1. Title 42. The Public Health and Welfare, Chapter 61. The Public Health Service Preventive Health Measures with Respect to Breast and Cervical Cancers 42 U.S.C. § 300k, 1996. Available at http://www.cdc.gov/cancer/nbccedp/bccpdfs/uscodebc.pdf.

2. Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) and the WISEWOMAN legislative supplement. Available at http://www.cdc.gov/wisewoman/legislation_highlight.htm.

3. Indian Self-Determination and Education Assistance Act, Public Law 93-638. Available at http://www.oiephr.bia.edu/Adobe/Training%20Handouts/Public%20Law%2093-638.pdf.

4. Health Insurance Portability and Accountability Act of 1996 (HIPAA). Available at http://www.cms.hhs.gov/hipaa/.

5. Code of Federal Regulations, Title 45. See Part 74 (Uniform Administration Requirements, Part 92 (Uniform Administration Requirements, State and Local Governments), and Part 93 (New Restrictions on Lobbying). Available at http://www.hhs.gov/grantsnet/adminis/fedreg45.htm.

6. CDC/ATSDR Committee on Community Engagement. *Principles of Community Engagement.* Atlanta: CDC, Public Health Practice Program Office, 1997. Available at http://www.cdc.gov/phppo/pce/index.htm.

7. University of North Carolina's (UNC's) Center for Health Promotion and Disease Prevention. *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program.* Chapel Hill, NC: UNC, 2001. Available at http://www.hpdp.unc.edu/wisewoman/.

8. Center for Medicare and Medicaid Services. Available at http://www.cms.hhs.gov/.

9. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *Executive Summary of the Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel III). NIH Publication No. 01-3670. Bethesda, MD: National Heart, Lung, and Blood

Institute, 2001. Available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm.

10. Joint National Committee. *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7). NIH Publication No. 04-5230. Bethesda, MD: National Heart, Lung, and Blood Institute, 2004. Available at http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm.

11. WISEWOMAN Web board. Available at http://wisewoman.forum.cdc.gov.

12. PHS Grants Policy Statement ("the yellow book"), April 1994. Available at http://grants.nih.gov/grants/policy/gps.

13. WISEWOMAN/Research Triangle Institute Web page (minimum data elements, cost data, user's guide, reports, and other documents). Available at https://wisewoman.rti.org/.

14. Request for Applications, Program Announcement 03022, Component 3. Available at http://www.cdc.gov/nccdphp/pdf/PA03022.pdf (also located at Appendix D).

15. CDC Human Research Protection Office Web page. Available at http://www.cdc.gov/od/ads/hsr2.htm.

Additional Resources

HHS Federal Grants Orientation Web page. Available at http://www.knownet.hhs.gov/grants/orientDR/learn.htm.

CDC Freedom of Information Act policy, July 14, 1995. Available at http://www.cdc.gov/od/foia/policies/foia.pdf.

CDC Procedures for Protection of Human Research Participants, October 1997. Available at http://www.cdc.gov/od/foia/manuals/procphrp.pdf.

Application for federal assistance (SF 424A) and financial status report (FSR) forms available from the Office of Management and Budget. Available at http://www.whitehouse.gov/omb/grants/grants_forms.html.

Office for Human Research Protections (OHRP) Web page. Available at http://www.hhs.gov/ohrp/.

3

Setting Up Your Screening and Referral Services

Chapter 3: Setting Up Your Screening and Referral Services

This chapter provides you with the information your project needs to establish screening services for WISEWOMAN participants. The first section focuses on requirements specific to the WISEWOMAN program, and the last section contains national clinical care and prevention guidelines for providing screening and follow-up services to WISEWOMAN participants.

WISEWOMAN Program Guidelines

Participants

All women aged 40 or older who are enrolled and remain eligible to participate in the state, territory, or tribal Breast and Cervical Cancer Early Detection Programs (BCCEDP) are eligible to participate in WISEWOMAN. A WISEWOMAN participant is a woman who meets the eligibility criteria and has

- Signed the consent form.
- Answered health behavior questions (e.g., on a health-risk appraisal form, lifestyle questionnaire, or enrollment form).
- Been screened for at least one risk factor for heart disease or stroke.

Who Counts?

When we analyze your data to see if you are meeting your screening performance indicator (i.e., number of women screened), you probably wonder who counts toward meeting this goal. Even if you submit data on just one risk factor, that woman counts! However, we expect that you will submit any missing data (e.g., missing cholesterol or glucose test results) as soon as the data are made available. Keep in mind, each WISEWOMAN participant must complete the screening requirements before she can take part in the lifestyle intervention (LSI).

Screening Guidelines

Policy on Allowable Screening Tests

WISEWOMAN funds can be used for the following tests:

- Resting pulse.
- Blood pressure.
- Serum total cholesterol (nonfasting).
- High-density lipoprotein cholesterol (HDL-C) (nonfasting).
- Height and weight measurements.
- Panels that include assessment of blood glucose.
- Urine analysis, including a test for urine cotinine.
- Paper-and-pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

If a woman is fasting during her screening visit, a **fasting lipoprotein analysis** is allowed and should be conducted to determine cholesterol level, and a **fasting plasma glucose** is allowed and should be conducted to determine her glucose level.

Policy on Allowable Office Visits

WISEWOMAN funds can be used to reimburse a maximum of two office visits per year for each participant. The content of the office visits will be consistent with the intent of a screening program rather than a treatment program. However, at the discretion of your project, these office visits may be used to provide more in-depth counseling about risk reduction; to reassess whether blood pressure, glucose, or cholesterol goals have been met as a result of completing the lifestyle intervention; to conduct allowable diagnostic testing; or to provide WISEWOMAN screening.

Policy on Allowable Diagnostic Tests

WISEWOMAN funds can be used for the following diagnostic tests: fasting lipoprotein panel and fasting plasma glucose (FPG) measurement or oral glucose tolerance test (OGTT).

Policy on A1C Testing

For women with previously diagnosed diabetes, projects may use WISEWOMAN funds to pay for A1C (glycosolated hemoglobin) testing in lieu of a fasting plasma glucose test. This test, as with all other tests conducted at the initial screening visit, will be performed again 1 year (10–14 months) later at the evaluation (first annual) screening visit.

Fasting vs. nonfasting. A complete lipoprotein profile (total cholesterol, low-density lipoprotein cholesterol [LDL-C], high-density lipoprotein cholesterol [HDL-C], and triglycerides), which requires a 9- to 12-hour fast, is the preferred cholesterol test, according to the Adult Treatment Panel III (ATP III).[1] The American Diabetes Association recommends that an 8-hour fast occur before testing fasting blood glucose.[2] We encourage you to work with your health care practitioners to meet these recommendations. To enable your project to screen the maximum number of women, the WISEWOMAN program does allow projects to report nonfasting total cholesterol, HDL-C, and blood glucose. However, a woman who has abnormal values for any of the nonfasting tests will be referred or asked to return for a fasting (diagnostic) measure.

Risk-reduction counseling. After each screening visit, the participant will receive risk-reduction counseling as part of the screening protocol. Risk-reduction counseling provides the participant with an interpretation of the results of her screening tests and health-risk-assessment questions. During these counseling sessions, we strongly recommend that for all women, you use easy-to-understand language both orally and in writing. Risk-reduction counseling is not considered to be part of a project's lifestyle intervention (LSI) because all women, regardless of whether or not they agree to attend the LSI sessions, should receive information on their screening results.

During the initial screening visit, each woman should be informed that she will be asked to participate in the project's health-promoting LSI and that she will need to return to complete an evaluation (first annual) screening visit in 10–14 months.

Protocol Development

To develop your screening protocol (also known as standard operating procedures), use the information in this chapter on allowable office visits and allowable tests in conjunction with the protocol guidance provided in Chapter 2. Also consult with your public health advisory committee and review the list of CPT codes in Appendix C. These codes relate to the allowable tests and office visits discussed in this chapter.

Baseline or initial screening. At a minimum, the health care practitioner must measure and report to CDC each participant's blood pressure (two readings), total cholesterol and HDL-C, and height and weight, along with the additional data needed to meet the program's required minimum data elements (MDEs). This information includes medical history; medication use; and health behaviors related to diet, physical activity, and tobacco use.

We highly recommend that projects also screen for diabetes because this disease is an extremely important risk factor for cardiovascular disease. If WISEWOMAN funds are used for blood glucose or A1C testing, the results of these tests should also be reported. These MDEs are collected at the baseline, evaluation (first annual), and annual office visits, and they are submitted semiannually to Research Triangle Institute, the WISEWOMAN program's evaluation contractor.

During the initial screening visit, each woman should be informed that she will be asked to participate in the project's health-promoting LSI and that she will need to return to complete an evaluation (first annual) screening visit in 10–14 months. This information should be included in the consent form. These activities should be offered to **all** women, not just those with abnormal screening values.

Remind-Her Systems

Start with the consent form: It should inform each woman that she will be asked to return for the evaluation (first annual) screening visit. The consent form should also inform her of the benefits of attending the LSI. Other reminder systems, such as telephone calls, postcards, or letters, are also needed to remind women about appointments.

Interim or mid-year screening. If you have an enhanced WISEWOMAN project, we strongly encourage you to include an interim rescreening office visit in your study design. This visit occurs once the participant has completed all LSI sessions. The screening tests and health behavior questions collected at baseline are collected again at this office visit. This visit will provide an additional data point that will strengthen the quality of data used to evaluate the effectiveness of all WISEWOMAN projects and the WISEWOMAN program overall. If you make an interim screening visit part of your research design, your enhanced project is **exempt** from counting this office visit toward the two-office-visit limit.

Some standard WISEWOMAN projects have asked that participants who have completed the LSI be allowed to return to their provider before the evaluation (first annual) screening visit to determine if these women have met their blood pressure or cholesterol goals. Some projects may be able to provide this type of feedback without incurring the cost of an office visit (e.g., by measuring blood pressure during an LSI session). The interim office visit can only be reimbursed if this visit does not exceed the program limit of two office visits per participant per year.

Evaluation (first annual) screening. Although national guidelines might indicate that a woman with a normal screening value does not need to be rescreened 1 year later (guidelines recommend 2 years for normal blood pressure, 5 years for normal cholesterol, and 3 years for normal glucose), the WISEWOMAN program requires an evaluation screening 1 year after the baseline screening to facilitate program evaluation.

CDC has established that a minimum of 75% of new women screened should return for the evaluation screening within 10–14 months from the baseline screening visit. Therefore, every effort should be made to have women return for this evaluation screening.

We have been asked a couple of questions related to this office visit:

- "Is it appropriate to cease reminding women about this office visit once the 14-month period has passed?" **Yes, this would be acceptable.**
- "If a woman does return to complete the evaluation screening at 15 months or later, should her results be included with the minimum data element submission?" **Yes, we still want these data to be sent to Research Triangle Institute.**

Why Does the WISEWOMAN Program Place Such a Great Emphasis on Completing the Evaluation Screening?

This visit is critical for program evaluation. If only a few women return for the evaluation screening, we cannot know for sure what impact the WISEWOMAN program is having. For example, the few women who do return might not represent all women who received the screening. Changes in risk factors among the returning women could differ from changes among those who didn't return for the evaluation screening. Therefore, it is imperative that you work with participants and providers to ensure that as many women as possible return for the evaluation screening. This will help us assess the program's true effects.

Policy on Evaluation (First Annual) Screening Visit

A system must be in place to track all new WISEWOMAN participants, regardless of screening results, to remind them to return for their evaluation (first annual) screening, which occurs 10–14 months after the initial screening. At least 75% of all new women screened will return for the evaluation screening. The evaluation screening will consist of the same screening tests that were completed at baseline and will use the same health behavior questions asked during the initial visit (these are reported as minimum data elements).

Annual screening. WISEWOMAN funds may be used to reimburse your project for annual screenings that occur beyond the initial and evaluation (first annual) screening for women who are still eligible to participate in the program. The data requirements for these annual screenings are the same as for the initial and evaluation screening visits. We encourage you to work with your public health advisory committee to establish your annual screening visit protocol.

Medical Referrals for Women with Abnormal Values

Policy on Medical Referrals for Women with Abnormal Values

A major responsibility of your project staff is to ensure that women with abnormal screening values are referred to a health care provider for appropriate diagnostic examinations in accordance with national and program guidelines. You do not need to submit results from this office visit to CDC, but you will want to periodically review the referral data to detect any problems with your referral system.

When a woman has a screening value that is abnormal but not in the alert range (see *alert values* in next section), you should refer her to a medical care system for diagnostic testing or evaluation in accordance with national guideline recommendations. This office visit counts as one of the two allowable office visits per participant per year. (Note: the first annual screening does not count because it occurs after a new year begins.) However, if the participant completed a fasting lipid panel and fasting blood glucose at the initial/baseline office visit, additional diagnostic exams should not be reimbursed with WISEWOMAN funds. In addition, the medical care system that the woman is referred to is responsible for providing medical follow-up and ensuring treatment.

If the participant completed a fasting lipid panel and fasting blood glucose at the initial/baseline office visit, additional diagnostic exams are not required and thus should not be reimbursed with WISEWOMAN funds.

Because the WISEWOMAN program focuses on health promotion and primary prevention, we require that you send CDC the results of the baseline or initial screening visit but not the results of the follow-up or diagnostic exam office visit. For the same reason, you cannot use WISEWOMAN funds to track or ensure that each woman follows through with the diagnostic examination unless she had an alert screening value. Although the care of each woman who has an abnormal (nonalert) value is not tracked by the project or funded by CDC, you will want to periodically monitor or review providers' referral procedures to ensure that women are being referred to needed follow-up care in a timely manner.

Monitor Care Given to Women with Alert Screening Values

We established ***alert values*** during the first phase of WISEWOMAN (1995–1998) after reviewing national research studies to determine how they managed people with dangerously high blood chemistry measurements.[3,4]

We modeled WISEWOMAN's alert values for cholesterol and glucose on the panic values established by the National Health and Nutrition Examination Survey III (NHANES III).[3] NHANES III defines panic values as >400 mg/dL for cholesterol and >375 mg/dL for glucose.

WISEWOMAN's alert value for blood pressure is based on guidance from the *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7).[4] Extremely high blood pressure can be deadly if left untreated for even a short time. Therefore, the JNC 7 recommends that a systolic blood pressure of >180 mm Hg or a diastolic blood pressure of >110 mm Hg be evaluated and treated immediately or within 1 week, depending on the clinical situation.

WISEWOMAN's Alert Screening Values

- Systolic blood pressure >180 mm Hg*.
- Diastolic blood pressure >110 mm Hg*.
- Total Blood Cholesterol >400 mg/dL.
- Blood glucose >375 mg/dL.

* To determine if a systolic or diastolic blood pressure is an alert value, your screening providers may use the ***average*** of the two systolic or diastolic measures.

Your project must submit the following data for each woman who has an alert screening value: (1) the referral date, (2) the diagnostic exam date, and (3) whether medication was prescribed. The WISEWOMAN program uses this information to monitor the following:

- **Number of women who have an alert screening value.**
- **Percentage of women with an alert screening value who have been referred to a health care provider.** Our standard is 100%.
- **Number of days between screening and referral.** We recommend that the referral call be made the day of screening.

- **Percentage of women who follow through with the referral and complete their follow-up/diagnostic appointment.** Our standard is 95% or higher. Case management should be provided, if needed.
- **Number of days from the screening visit to the follow-up/diagnostic visit.** The follow-up visit should occur immediately or within 1 week, according to WISEWOMAN program policy.
- **Percentage of women who receive pharmaceutical treatment.** We recommend that all women with alert values receive treatment in accordance with national clinical care guidelines.

If women with alert values are not receiving care in accordance with national and program guidelines, your project should conduct a special study or audit to determine if your referral procedures or provision of care needs improvement.

Policy on Medical Referral and Documentation for Women with Alert Values

Women with alert screening values must be evaluated and treated immediately or within 1 week, depending on the clinical situation, in accordance with national and program guidelines. For each woman with an alert value, you must document her referral date, diagnostic exam date, and if the medication was prescribed as a minimum data element and submit these data semiannually to Research Triangle Institute.

WISEWOMAN-Funded Case Management

Policy on Case Management

Although WISEWOMAN supports the use of case management to improve adherence to national clinical care guidelines, your project should offer WISEWOMAN-funded case management services only to women with alert values. WISEWOMAN-funded case management services must end when a woman begins receiving prescribed treatment or is no longer eligible for the WISEWOMAN program.

WISEWOMAN defines case management in the same way as the *National Breast and Cervical Cancer Early Detection Program Policies & Procedures Manual* [5] defines it:

> A program component that involves establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and essential support services for all NBCCEDP enrolled women who would ultimately be assessed to need case management services. Throughout this policy, the term "client" refers to women in the NBCCEDP program who have a demonstrated need for case management, the most intensive intervention in the continuum of care. CDC expects that the proportion of case management clients in the program will be small compared with all the women being served by the NBCCEDP.

Case management is one strategy for ensuring that women with alert values are screened at appropriate intervals, that they access appropriate diagnostic services to address their alert values, and that they receive appropriate medical treatment as needed. As noted in the definition above, case management is the most intensive support service offered. Professional standards of case management should be applied if this service is offered.

*Key Elements of Individual Case Management**

1. A cooperative effort between the client and case manager to examine the client's needs.
2. Development of a written plan for case management.
3. Brokerage of services, coordination of services, and referral to services.
4. Reassessments of the case management plan.
5. Promotion of the client's self-sufficiency.
6. Evaluation of the quality of the case management plan.

* Source: *National Breast and Cervical Cancer Early Detection Program Policies & Procedures Manual,* page iv-57.[5]

Because 60%–80% of WISEWOMAN participants can have abnormal screening values, the use of federal funds to provide clinical case management to all women with abnormal screening values is neither practical nor cost-efficient. This is why WISEWOMAN-funded case management services should be offered only to women with alert values. Similar to the NBCCEDP, WISEWOMAN expects that only a small portion of the women served by the program will receive case management. In 2004, less than 1% of the women screened had an alert screening value (70 women of 21,627 women screened).

Treatment and Access to Medication

By law, WISEWOMAN funds cannot be used for treatment. Therefore, therapeutic interventions, such as medication and medical nutrition therapy, cannot be reimbursed with WISEWOMAN funds. Your project can, however, work with health care practitioners to ensure that women have access to the recommended medical evaluation and treatment, including low-cost or free prescription medications (Table 3.1).

Policy on Access to Medication
Although you cannot use WISEWOMAN funds for treatment, including medication, you must develop a system to ensure access to medications for women who require this augmentation to lifestyle or behavior changes. You should describe this system in your project's protocol.

Although you cannot use WISEWOMAN funds for treatment, you are allowed to use these funds for the LSI because this activity is considered to be health education, not treatment.

WISEWOMAN funds cannot be used to reimburse for therapeutic interventions, such as medication, medical nutrition therapy, or diabetes self-management education. However, you are allowed to use these funds for the LSI because this activity is considered to be health education, not treatment.

Table 3.1. Patient and Physician Resources for Discounted and Free Medication*

Resource	Description	Contact Information
340B Drug Discount Program[6]	A Health Resources and Services Administration program that gives certain federally funded grantees access to low-cost pharmaceutical drugs.	http://bphc.hrsa.gov/opa/
Cost Containment Institute[8]	*Free and Low-Cost Prescription Drugs, 7*th edition, a 48-page booklet that gives information on how and where to obtain free and low-cost prescription drugs.	http://www.institutedc.org/orderbycc.htm
PhRMA Directory of Patient Assistance Programs[9]	A directory of Pharmaceutical Research and Manufacturers of America members who ensure access to medicines to people who cannot afford to purchase them.	http://www.phrma.org/searchcures/dpdpap/
Rx Access[10] (used by the South Dakota WISEWOMAN project)	Rx Access helps people gain access to drug company assistance programs that supply prescription medications at low or no cost. In addition, a pharmacist will review all medications a person is taking and may consult with a person's doctor, if necessary.	http://www.state.sd.us/social/asa/rxaccess/
Rx Assist[11]	A Web site developed by Volunteers in Health Care, a program of the Robert Wood Johnson Foundation, to provide health care practitioners with information on how to access programs that offer a limited supply of free or low-cost medications.	http://www.rxassist.org/default.cfm
Rx Hope[12]	A free program that helps physicians' offices apply for, obtain, and track requests for no-cost medications offered by federal, state, and charitable organizations.	Telephone: (908) 713-7600
State Pharmaceutical Assistance Programs[13]	A Web site that identifies states that have programs to provide pharmaceutical coverage or assistance, primarily to low-income older people or people with disabilities who do not qualify for Medicaid.	http://www.ncsl.org/programs/health/drugaid.htm
The Medicine Program[14]	A program that helps patients apply to pharmaceutical companies' indigent patient programs.	Telephone: (866) 694-3893

* Links to nonfederal organizations in this document are provided solely as a service to our users. These links do not constitute endorsements of these organizations or their programs by CDC or the federal government, and none should be inferred. CDC is not responsible for the content of the individual organizations' Web pages found at these links.

Clearing Women to Participate in the Lifestyle Intervention

Health care and screening providers should be made aware that WISEWOMAN participants are expected to participate in the LSI. Provider training should include information on the goals and objectives of the LSI. Providers can play a key role in encouraging participants to follow through and complete the LSI sessions.

Your project's protocol must describe how women are referred to the LSI. There are many ways to do this, as the following examples show:

- You could work with provider offices that have a health educator/ nutritionist/nurse on staff who provides the first LSI session while the participant is in the office for her cardiovascular and other chronic disease risk factor screening appointment.
- You might require the screening provider to use a "prescription pad" to indicate the importance of good nutrition, physical activity, and tobacco cessation to the participant. The "prescription" would then recommend that the woman participate in the LSI program designed to help her adopt healthy lifestyle habits.
- You could use the consent form to make the participant aware of the LSI and then have intervention staff contact her as soon as screening results have been received to make an appointment for her to attend the LSI sessions.

The physical activity component of the LSI will likely encourage the participant to increase her level of moderate-intensity physical activity, such as walking and doing house and yard work. To screen for women who might have an adverse outcome from moderate-intensity activities, we suggest asking her a few questions. One tool that projects may want to review for use in clearing women for physical activity is the Physical Activity Readiness Questionnaire (PAR-Q). The British Columbia Ministry of Health developed the original PAR-Q, and an Expert Advisory Committee of the Canadian Society for Exercise Physiology revised the questionnaire in 2002. The PAR-Q contains seven questions and can be accessed at http://www.csep.ca/pdfs/par-q.pdf.[15]

The North Carolina WISEWOMAN project has worked with the University of North Carolina to adapt the PAR-Q to meet its project's needs. The following questions are included in the project's consent form:

1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?
   ☐ yes ☐ no

2. Do you feel pain in your chest when you do physical activity?
   ☐ yes ☐ no

3. In the past month have you had chest pain lasting more than one minute when you were not doing physical activity?
   ☐ yes ☐ no

4. Do you lose your balance because of dizziness or do you ever lose consciousness?
   ☐ yes ☐ no

5a. Is your doctor currently prescribing drugs for your blood pressure or heart condition (for example, water pills)?
   If yes, go to 5b.

5b. If so, is your blood pressure or heart condition UNDER CONTROL?
   ☐ yes ☐ no

6. Do you know of any other reason why you should not do physical activity?
   ☐ yes ☐ no

If the participant answers YES to any one of the questions 1 through 4 or 6 (above), or if the answer to question 5b is no, she will be referred to her clinician for permission to participate in the physical activity portion of the project.

Data Systems Needed to Track Screening Activities

At a minimum, projects need to have systems in place that allow them to

- Identify and screen BCCEDP participants who are 40 years of age or older (a process known as "inreach" within the NBCCEDP).
- Submit accurate, complete, and timely MDEs.
- Notify participants of their screening results, ideally in plain language, both verbally and in writing.
- Identify health care practitioners willing to provide follow-up care to WISEWOMAN participants who have abnormal screening results.
- Ensure that women who have alert screening values are evaluated immediately or within 1 week, depending on their clinical situation.
- Ensure that case management is available for every participant who has an alert screening value. The case manager can help the participant navigate the health care system to ensure that she receives timely follow-up care.
- Monitor women with alert values to find out when they received follow-up care and if they were prescribed medication in accordance with national and program guidelines.
- Know who has completed the initial screening and is thus eligible to participate in the health-promoting LSI. (See Chapter 4, which describes tracking needs for the intervention component of your project.)
- Notify participants that they need to return for their evaluation screening visit 1 year (10–14 months) after the baseline screening. Many projects mail reminders to participants and/or call them.

Evaluating Screening Activities

The WISEWOMAN program encourages your project to develop a quality assurance plan and methods that support continuous quality improvement. Your protocol should describe the quality assurance activities you plan to implement and they should also be reflected in your work plan.

Quality assurance typically means ensuring that standards of quality are being met. For example, quality assurance plans should specify that projects only contract with providers who send their blood draws to labs that are CLIA-approved. If CLIA-waived equipment to test cholesterol levels are used, then the quality assurance plan should specify ways to ensure that the users of these machines are trained on how to calibrate and use them.

For additional information on evaluation, see Chapter 5.

National Clinical Care and Prevention Guidelines

Adherence to National Guidelines

Policy on Ensuring Adherence to National Guidelines

To ensure that participants receive high-quality care, your project should contract only with health care practitioners who agree to provide care in accordance with national clinical care and prevention guidelines. In addition, your project should offer these practitioners professional development opportunities that promote the use of national guideline recommendations.

In addition to offering professional development opportunities, your project can use several other methods to ensure that health care practitioners adhere to national clinical care and prevention guidelines:

- In your contracts with health care practitioners, include language that calls for adherence to clinical care guidelines.
- Work with the practitioners' public heath advisory committee to develop screening protocols.
- Establish mechanisms for providing feedback to health care practitioners on how well they are adhering to these guidelines.

Table 3.2. National Guidelines Aimed at Modifying Risk Factors for Cardiovascular and Other Chronic Diseases

Risk Factor	Guidelines and Web Links*
High blood pressure	The *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7)[4] http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm
High cholesterol	National Cholesterol Education Program, Adult Treatment Panel III Report (ATP III)[1] http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines[16] http://rover2.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm
Poor nutrition	*Dietary Guidelines for Americans*[17] http://www.healthierus.gov/dietaryguidelines/ ATP-III TLC diet principles[16] http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm DASH eating plan (JNC 7)[18] http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/
Low levels of physical activity	CDC/American College of Sports Medicine (ACSM) recommendations[19] http://www.cdc.gov/nccdphp/dnpa/physical/recommendations/older_adults.htm Surgeon General's recommendations for physical activity[20] http://www.cdc.gov/nccdphp/sgr/contents.htm The Task Force on Community Preventive Services systematic reviews of community interventions to increase physical activity[21] http://www.thecommunityguide.org/pa/default.htm
Overweight and obesity	Obesity Education Initiative's guidelines for weight management[22] http://www.nhlbi.nih.gov/about/oei/ *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*[23] http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm
Tobacco use	U.S. Department of Health and Human Services *Clinical Practice Guideline: Treating Tobacco Use and Dependence: A Systems Approach*[24] http://www.surgeongeneral.gov/tobacco/default.htm
Diabetes	American Diabetes Association Clinical Practice Recommendations 2005[2] http://www.diabetes.org/for-health-professionals-and-scientists/cpr.jsp

* The WISEWOMAN program recognizes that these are guidelines or recommendations and that a responsible physician's judgment remains paramount.

Screening for High Blood Pressure

Providers should follow the recommendations of the *Seventh Report of the Joint National Committee on Prevention Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7) (http://nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm).[4]

The prevention and management of hypertension are major public health challenges for the United States. The prevalence of hypertension increases with advancing age: more than half of people aged 60–69 years old and approximately three-fourths of those aged 70 years or older have high blood pressure.[4]

Several factors that contribute to hypertension have been identified, including being overweight; consuming too much sodium; not getting enough physical activity; not consuming enough fruits, vegetables, and potassium; and drinking too much alcohol. Primary prevention measures are needed to reduce or minimize these causal factors in the population. A population approach that decreases the blood pressure level in the general population by even modest amounts could substantially delay the development of hypertension and reduce illness and deaths from heart disease and stroke.

The prevalence, impact, and control of hypertension differ across racial and ethnic subgroups of the U.S. population. For example, hypertension is more common and more severe, develops at an earlier age, and has greater health consequences among African Americans than among non-Hispanic whites.[4] Control of blood pressure is less common among Mexican Americans and Native Americans than among non-Hispanic whites and African Americans. As a result, WISEWOMAN projects will want to incorporate culturally appropriate strategies to reach out and recruit women from minority racial and ethnic groups.[4]

WISEWOMAN projects should incorporate culturally appropriate strategies to reach out and recruit women from minority racial and ethnic groups.

Accurate blood pressure measurement. Accurate blood pressure measurement is critical for detecting and managing high blood pressure. The JNC 7 report recommends the following steps for accurately measuring blood pressure:

1. Clients should not smoke, exercise, or have caffeine for at least 30 minutes before their blood pressure is measured.

2. Clients should be seated quietly for at least 5 minutes in a chair (rather than on an exam table), with feet on the floor and arms supported at heart level.

3. To ensure accuracy, use an appropriate size cuff (cuff bladder encircling at least 80% of the arm). Many adults will require a large adult cuff.

4. Use a mercury sphygmomanometer, a recently calibrated aneroid manometer, or a validated electronic device to measure blood pressure.

5. Systolic blood pressure (SBP) is the point at which the first of two or more sounds is heard (phase 1), and diastolic blood pressure (DBP) is the point before the disappearance of sounds (phase 5).

6. Measure and record **at least two measurements,** separated by a minimum of 2 minutes. If the first two readings differ by more than

5 mm Hg, obtain additional readings (per JNC 6). **WISEWOMAN requires that two measurements be reported.**

7. Clinicians should give each client specific blood pressure numbers and goals, both verbally and in writing.

Table 3.3 provides a quick reference guide for evaluating the blood pressure of WISEWOMAN participants. This table incorporates JNC 7 recommendations as well as WISEWOMAN program guidance.

Table 3.3. Blood Pressure Screening for WISEWOMAN Participants

Classification*	Systolic Blood Pressure (mm Hg)	Diastolic Blood Pressure (mm Hg)	WISEWOMAN Funds May Be Used to Reimburse for These Required Follow Up Activities†
Normal	<120	and <80	• Refer participant to structured WISEWOMAN lifestyle intervention (LSI) to help her adopt and maintain healthy lifestyle practices. • Recheck blood pressure 1 year after baseline screening for program evaluation.§
Pre-hypertension	120–139	and 80–89	• Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices and avoid developing hypertension. • Recheck blood pressure 1 year after baseline screening for program evaluation.
Stage 1 Hypertension	140–159	or 90–99	• Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Refer to confirm blood pressure within 2 months. • Recheck blood pressure 1 year after baseline screening for program evaluation.
Stage 2 Hypertension	≥160	or ≥100	• Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Refer participant for blood pressure reevaluation within 1 month. • Recheck blood pressure 1 year after baseline screening for program evaluation.
Alert value as identified by WISEWOMAN program (subset of Stage 2)	>180	or >110	• Refer participant for follow-up care **and track** to ensure that she is evaluated and treated immediately or within 1 week, depending on clinical situation. • Provide case management, if needed. • Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Recheck blood pressure 1 year after baseline screening for program evaluation.

* If systolic and diastolic categories are different, follow recommendations for shorter time follow-up (e.g., a woman with a reading of 160/86 mm Hg should be evaluated or referred to source of care within 1 month).

† Modify the scheduling of follow-up according to reliable information about past blood pressure measurements, other cardiovascular risk factors, or target organ disease as defined by JNC 7. WISEWOMAN funds may be used to reimburse a maximum of two office visits per year per participant. This means that the initial screening visit and a referral/follow-up office visit to confirm or diagnose high blood pressure can be reimbursed by the program. The evaluation (first annual) screening visit occurs in the next screening year.

§ Although the JNC 7 guidelines recommend a 2-year interval for people who have normal blood pressure, the WISEWOMAN program requires that women return 1 year (10–14 months) after their baseline screening visit to collect data for purposes of program evaluation.

Screening for High Blood Cholesterol

Providers should follow the recommendations of the National Cholesterol Education Program's (NCEP) Adult Treatment Panel III (ATP III) Report[1] for treating high blood cholesterol in adults (http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm) and view the July 2004 update to these guidelines (http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm).[16]

ATP III recommends a complete lipoprotein profile (total cholesterol, LDL-C, HDL-C, and triglycerides, conducted after a 9- to 12-hour fast) as the preferred initial test, rather than total cholesterol and HDL-C alone.

The ATP III Report states that a clinical risk assessment has two goals: (1) to identify people who are at risk for accelerated atherogenesis and (2) to identify those who are at higher risk for acute coronary syndrome because of established advanced atherosclerosis. A feature of the ATP III Report is a focus on primary prevention of coronary heart disease in people with multiple risk factors.

Your WISEWOMAN project should strongly encourage health care practitioners to use ATP III recommendations to guide their care of WISEWOMAN participants with elevated cholesterol. To promote the use of these recommendations, you should work with your public health care advisory committee to develop protocols and provide training on ATP III guidelines for health care providers.

ATP III recommends a complete lipoprotein profile (total cholesterol, LDL-C, HDL-C, and triglycerides, conducted after a 9- to 12-hour fast) as the preferred initial test, rather than total cholesterol and HDL-C alone. Although the WISEWOMAN program also prefers this type of testing, we also recognize that WISEWOMAN screenings can occur during a breast and cervical cancer screening visit, when women are unlikely to have fasted. Consequently, WISEWOMAN allows projects to determine cholesterol levels by measuring nonfasting total cholesterol and HDL-C. For women who are otherwise at low risk (one or no risk factor), further testing is not required if their HDL-C level is $\geq$40 mg/dL and their total cholesterol is $<$200 mg/dL. However, for women with two or more risk factors, lipoprotein measurement is recommended as a guide to clinical management. (Providers should refer to Step 2 of *ATP III Guidelines At-A-Glance Quick Desk Reference*[25] [http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.pdf] to determine a participant's number of risk factors. The number of risk factors is used to determine if the Framingham 10-year risk for coronary heart disease should be calculated. The results of this calculation are then used to determine the LDL-C goal.)

Table 3.4 provides a quick reference for evaluating the cholesterol levels of WISEWOMAN participants. This table incorporates ATP III recommendations as well as WISEWOMAN program guidance.

Table 3.4. Cholesterol Screening for WISEWOMAN Participants

Classification	Total Cholesterol (mg/dL)	WISEWOMAN Funds May Be Used to Reimburse for These Required Follow Up Activities*
Desirable	<200	• Refer participant to structured WISEWOMAN lifestyle intervention (LSI) to help her adopt and maintain healthy lifestyle practices. • Refer participant for fasting lipid panel if screening test was nonfasting and HDL is <40 mg/dL. • Recheck cholesterol 1 year after baseline screening for program evaluation.
Borderline high	200–239	• Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Refer participant for complete fasting lipid panel if screening test was nonfasting. • Recheck cholesterol 1 year after baseline screening for program evaluation.
High	≥240	• Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Refer participant for complete fasting lipid panel if screening test was nonfasting. • Recheck cholesterol 1 year after baseline screening for program evaluation.
Alert value as identified by WISEWOMAN program	>400	• Refer participant for follow up care and track that she is evaluated and treated immediately or within 1 week, depending on clinical situation. • Provide case management if needed. • Refer participant to structured WISEWOMAN LSI to help her adopt and maintain healthy lifestyle practices. • Recheck cholesterol 1 year after baseline screening for program evaluation.

* Although the ATP III guidelines recommend a 5-year interval for people who have normal blood cholesterol, the program requires that women return 1 year after their baseline screening visit to collect data for purposes of program evaluation. WISEWOMAN funds may be used to reimburse a maximum of two office visits per year per participant. This means that the initial screening visit and a referral/follow-up office visit to confirm or diagnose high cholesterol can be reimbursed by the program. The evaluation (first annual) screening visit occurs in the next screening year.

Screening for Overweight and Obesity

Providers should follow the recommendations of the National Institutes of Health (NIH) *Practical Guide on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* (http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm).[23]

All overweight and obese adults (18 years of age or older) with a body mass index (BMI) of ≥25 are considered at risk for developing associated morbidities or diseases such as hypertension, high blood cholesterol, type 2 diabetes, coronary heart disease, and other diseases. Adults with a BMI of 25–29.9 kg/m^2 are considered overweight, and those with a BMI >30 kg/m^2 are considered obese.[23]

This guide provides health care practitioners with a step-by-step approach to treating overweight and obesity. Your project's public health advisory committee should review these guidelines and write the protocol accordingly. Many of the steps in this approach may be covered by the WISEWOMAN-funded LSI, which incorporates strategies to increase physical activity and includes behavioral strategies such as self-monitoring, stress management, problem-solving, and social support. Your project may address caloric intake by teaching participants how to choose sensible portion sizes and how to determine how many daily servings of each food group are needed for a healthy diet.

For women found to have a BMI between 25 and 34.9 kg/m^2, the health care provider should also measure waist circumference. A high waist circumference (>35 inches for women) is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and cardiovascular disease.[23]

Table 3.5 provides a quick reference guide for evaluating the weight of WISEWOMAN participants. This table incorporates recommendations from the *Practical Guide* as well as WISEWOMAN program guidance.

Table 3.5. Weight Screening for WISEWOMAN Participants

Classification	Body Mass Index (BMI)	WISEWOMAN Funds May Be Used to Reimburse for These Required Follow Up Activities
Underweight	<18.5 kg/m^2	• Refer participant to structured WISEWOMAN lifestyle intervention to promote healthy lifestyle habits. • Reassess body mass index 1 year after baseline assessment for program evaluation.*
Normal weight	18.5–24.9 kg/m^2	
Overweight	25–29.9 kg/m^2	
Obesity (Class 1)	30–34.9 kg/m^2	
Obesity (Class 2)	35–39.9 kg/m^2	
Extreme obesity (Class 3)	≥40 kg/m^2	

* Although the NIH guidelines recommend a 2-year interval for people who are not overweight, the WISEWOMAN program requires that women return 1 year after their baseline screening visit to collect data for purposes of program evaluation.

Did You Know?

If your WISEWOMAN project reimburses providers for diabetes screening, then all women participating in your project should be screened for diabetes.

Screening for Diabetes

When screening for diabetes, providers should follow the American Diabetes Association's (ADA's) 2005 Clinical Practice Recommendations, Screening for Type 2 Diabetes (http://www.diabetes.org/for-health-professionals-and-scientists/cpr.jsp).[2] Whereas the WISEWOMAN legislation mandates that all projects screen their participants for elevated blood pressure and cholesterol, the program strongly encourages projects to screen for diabetes, which is a risk factor for cardiovascular disease. Generally, the effectiveness and cost-effectiveness of screening asymptomatic populations for diabetes remains controversial, as the ADA notes in its recommendations.[2] Nevertheless, the ADA recommendations support the use of *opportunistic screening* in a clinical setting for people at high risk for diabetes.

CDC's Division of Diabetes Translation has determined that diabetes screening provided through WISEWOMAN constitutes opportunistic screening because the participant is screened within a health care facility, usually during an office visit for breast and cervical cancer screening. WISEWOMAN participants are often at higher risk for diabetes because of their age, weight, and physical inactivity. Therefore, the WISEWOMAN program allows your project to use WISEWOMAN funds for diabetes screening. Work with your public health advisory committee to determine whether or not your project will screen participants for diabetes, and make sure your protocol reflects this decision.

Which Test Is Preferred for Diagnosing Diabetes?

The FPG test is preferred for diagnosis of diabetes in clinical settings because it is easier and faster to perform, more convenient and acceptable to patients, and less expensive. OGTT is not recommended for routine clinical use. A1C is not a screening or diagnostic test, but is used to monitor glycemia.

Diagnostic testing. The fasting plasma glucose (FPG) test and the oral glucose tolerance test (OGTT) are both suitable tests for diagnosing diabetes; however, OGTT is not recommended for routine clinical use. The FPG test is preferred in clinical settings because it is easier and faster to perform, more convenient and acceptable to patients, and less expensive. Participants with an FPG of 126 mg/dL (7.0 mmol/l) or greater should be retested on a different day to confirm a diabetes diagnosis. If the participant has an FPG of less than 126 mg/dL (7.0 mmol/l) but is nonetheless suspected to have diabetes, an OGTT should then be performed. An OGTT value of 200 mg/dl (11.1 mmol/l) or greater is a positive test for diabetes and should be confirmed on a different day. The ADA and the WISEWOMAN program do not endorse the use of A1C (glycosolated hemoglobin) as a screening test.

The ADA defines fasting as not consuming food or beverages other than water for at least 8 hours before testing. Because many WISEWOMAN participants visit their provider after they have already eaten or had a beverage, WISEWOMAN allows projects to use nonfasting blood glucose testing. The ADA refers to such tests as *casual* plasma glucose measurements. In other words, the measurement is taken without regard to the time of the last meal. A casual plasma glucose level ≥200 mg/dL in someone who has symptoms of diabetes (e.g., excessive thirst, blurred vision, frequent urination, weight loss) is considered diagnostic of diabetes. A confirmatory FPG test or OGTT should be completed on a different day if the patient's clinical condition permits.

Hemoglobin A1C. Hemoglobin is the part of a red blood cell that carries oxygen to the cells and sometimes joins with the glucose in the bloodstream. Testing the hemoglobin A1C of a person who has diabetes allows the provider to measure the person's average blood glucose level over the past 2–3 months. Also referred to as A1C, the test shows the amount of glucose that sticks to the red blood cell, which is proportional to the amount of glucose in the blood. The A1C test values remain a valuable tool for monitoring glycemia, but it is not currently recommended for the screening or diagnosis of diabetes.

Table 3.6 provides a quick reference for evaluating the blood glucose levels of WISEWOMAN participants. The table incorporates ADA recommendations as well as WISEWOMAN program guidance.

Table 3.6. Diabetes Screening for WISEWOMAN Participants

Classification	Glucose (mg/dL)	WISEWOMAN Funds May Be Used to Reimburse for These Required Follow Up Activities†
Desirable	FPG* <100 OGTT* <140	• Refer participant to structured WISEWOMAN lifestyle intervention (LSI) to promote healthy lifestyle habits. • Recheck glucose 1 year after baseline screening for program evaluation.
Prediabetes	FPG 100–125 (impaired fasting glucose) or OGTT 140–199 (impaired glucose tolerance)	• Refer participant to structured WISEWOMAN LSI created to promote healthy lifestyle habits. • Refer participant if results are not clearly hyperglycemia to confirm results on a different day. • Recheck glucose 1 year after baseline screening for program evaluation.
Diabetes	FPG ≥126 OGTT >200 Casual >200 plus symptoms	• Refer participant to structured WISEWOMAN LSI created to promote healthy lifestyle habits.§ • Refer participant if results are not clearly hyperglycemia to confirm results on a different day. • Recheck glucose 1 year after baseline screening for program evaluation.
Alert value as identified by WISEWOMAN program	Fasting or casual >375	• Refer participant for treatment and monitor that she is evaluated and treated immediately or within 1 week, depending on clinical situation. • Provide case management if needed. • Refer participant to structured WISEWOMAN LSI created to promote healthy lifestyle habits.§ • Recheck glucose 1 year after baseline screening for program evaluation.

* FPG, fasting plasma glucose, which is the preferred screening test; OGTT, oral glucose tolerance test.

† Although the ADA recommends rechecking normal glucose in 3 years or sooner for high-risk individuals, the program requires that all women regardless of screening results return 10–14 months after initial screening for purposes of collecting evaluation data. WISEWOMAN funds may be used to reimburse a maximum of two office visits per year per participant. This means that the initial screening visit and a referral/follow-up office visit to confirm hyperglycemia can be reimbursed by the program. The evaluation (first annual) screening visit occurs in the next screening year.

§ Participants may need to be referred for diabetes self-management education or medical nutrition therapy. However, WISEWOMAN funds cannot be used to pay for these therapeutic interventions.

Screening for Tobacco Use

Providers should refer to the recommendations of Treating Tobacco Use and Dependence—Clinician's Package: A How-To Guide for Implementing the Public Health Service Clinical Practice Guidelines (available at http://www.surgeongeneral.gov/tobacco/clinpack.html).[26] These guidelines suggest that as little as 3 minutes of physician intervention with an adult who uses tobacco can increase by 50% that person's chances of quitting successfully. The guidelines further advise that because effective tobacco dependence treatments are available, every participant who uses tobacco should be offered at least one of these treatments:

- Participants **willing** to try to quit tobacco use should be provided treatments identified as effective in the U.S. Public Health Service guideline.
- Participants **unwilling** to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit.

WISEWOMAN participants should be advised to quit and then offered effective treatment options, which include a behavior modification program, social support, quitting advice, and, when appropriate, drug therapies. WISEWOMAN projects are encouraged to work with their providers and partners to offer these different options.

Many of the states that have a WISEWOMAN project also have a state quitline to which women should be referred. Some states even have what is referred to as a proactive quitline. A proactive quitline uses a referral form that contains the client's consent to counseling. The provider can fax this referral form directly to the quitline, and the quitline counselor can then call the client directly. Several meta-analyses have found that proactive telephone counseling is effective.[27–31] The current U.S. Public Health *Clinical Practice Guideline* and the *Guide to Community Preventive Services* both recommend proactive telephone counseling as a method to help smokers quit.[21, 29] Randomized, controlled trials have established the efficacy of such proactive interventions,

Brief Counseling Can Make A Difference!

Guidelines suggest that as little as 3 minutes of physician intervention with an adult who uses tobacco can increase by 50% that person's chances of quitting successfully.

with the most recent meta-analysis of 13 studies showing a 56% increase in quit rates when compared with self-help.[31] Proactive quitlines might provide some form of immediate reactive assistance when a tobacco user first calls, but they also provide more comprehensive services through outbound (proactive) calls. The outbound service, which often entails multiple follow-up sessions, is typically scheduled by agreement with the smoker.

Proactive Quitlines Work!

Proactive telephone counseling is proven effective, and both the U.S. Public Health *Clinical Practice Guideline* and the *Guide to Community Preventive Services* recommended proactive telephone counseling as a method to help smokers quit.

The 5 A's

The U.S. Public Health Service recommends that providers use something as brief as the **5 A's** with tobacco users at each of their office visits:

- **Ask about tobacco use.** Implement an office-wide system that ensures that, for ***every*** person at ***every*** clinic visit, tobacco-use status is queried and documented.
- **Advise to quit.** In a clear, strong, and personalized manner, urge every tobacco user to quit.
- **Assess willingness to make a quit attempt.** Ask every tobacco user if she is willing to make a quit attempt at the time (e.g., within the next 30 days).
- **Assist in quit attempt.** Help the person who smokes with a quit plan.
- **Arrange follow up.** Schedule follow-up contact, either in person or via telephone.

In this chapter, the information on tobacco cessation is specific to physician counseling. Additional information on strategies for helping WISEWOMAN participants quit smoking (e.g., quitlines) is in Chapter 4.

The 5 R's

For women who are not ready to quit, you can use the 5 R's:

- **Relevance.** Encourage the person who smokes to indicate why quitting is personally relevant.
- **Risks.** Ask the participant to identify potential negative consequences of tobacco use.
- **Rewards.** Ask the participant to identify potential benefits of stopping tobacco use.
- **Roadblocks.** Ask the participant to identify barriers or roadblocks to quitting.
- **Repetition.** Repeat this motivational intervention every time you interact with the participant. Tell tobacco users who have failed in previous quit attempts that most people make repeated quit attempts before they are successful.

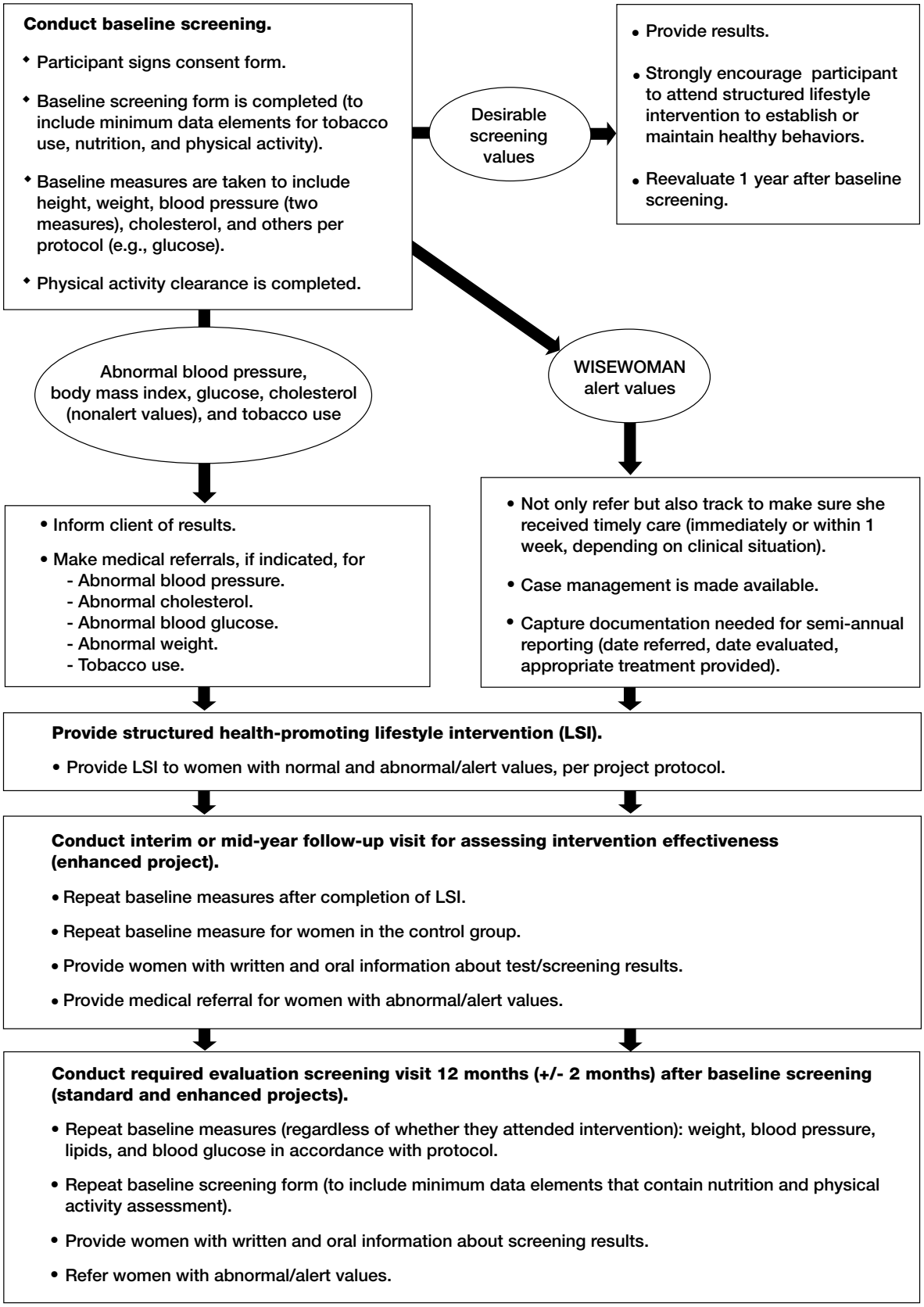
Screening for Nutrition and Physical Activity

Before or during the baseline screening, each woman is to complete the intake or enrollment form, which asks questions to assess the quality of her diet and her level of physical activity. For example, she is asked how many fruits and vegetables she consumes each day and how many minutes of moderate-intensity physical activity she completes on how many days each week. We encourage providers to make recommendations based on each participant's responses and to encourage the participant to complete the LSI. (See Chapter 4 for details about the LSI.)

Overview of Project Screening and Referral Responsibilities

The following flow diagram provides an overview of project responsibilities with regard to screening and referral. This program flow diagram was adapted from the University of North Carolina's WISEWOMAN manual.[32]

Figure 3.1. Summary of Project Screening and Referral Responsibilities



References

1. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *Executive Summary of the Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (Adult Treatment Panel III). NIH Publication No. 01-3670. Bethesda, MD: National Heart, Lung, and Blood Institute, 2001. Available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm.

2. American Diabetes Association. Clinical Practice Recommendations. *Diabetes Care* (serial online) 2005;28(Suppl 1):S1-79. Available at http://www.diabetes.org/for-health-professionals-and-scientists/cpr.jsp.

3. National Institutes of Health. *Total Cholesterol, Direct HDL, Precipitated HDL, Triglycerides, and LDL-NHANES 2001–2002.* Laboratory Procedure Manual. Bethesda, MD: NIH. Available at http://www.cdc.gov/nchs/data/nhanes/nhanes_01_02/l13_b_met_lipids.pdf.

4. Joint National Committee. *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7). NIH Publication No. 04-5230. Bethesda, MD: National Heart, Lung, and Blood Institute, 2004. Available at http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm.

5. National Breast and Cervical Cancer Early Detection Program. *Policies & Procedures Manual.* Atlanta: CDC, 2000.

6. Health Resources and Services Administration. 340B Drug Discount Program. Available at http://bhpc.hrsa.gov/opa/.

7. CNET Networks. MySimon Prescription Drugs. Available at http://www.mysimon.com/category/index.jhtml?c=prescriptiondrugs.

8. Cost Containment Institute. *Free and Low-Cost Prescription Drugs.* 7th edition. Available at http://www.institutedc.org/orderbycc.htm.

9. Pharmaceutical Research and Manufacturers of America. PhRMA Directory of Patient Assistance Programs. Available at http://www.phrma.org/searchcures/dpdpap/.

10. South Dakota Department of Health. RxAccess. Available at http://www.state.sd.us/social/asa/rxacess/.

11. Volunteers in Health Care. Rx Assist. Available at http://www.rxassist.org/default.cfm.

12. Rx Hope. Available at http://www.rxhope.com/.

13. National Conference of State Legislatures. State Pharmaceutical Assistance Programs. Available at http://www.ncsl.org/programs/health/drugaid.htm.

14. The Medicine Program. Available at www.themedicineprogram.com.

15. Expert Advisory Committee of the Canadian Society for Exercise Physiology. Physical Activity Readiness Questionnaire—PAR-Q (revised 2002). *PAR-Q & You.* Ottawa, Ontario: Canadian Society for Exercise Physiology, 2002. Available at http://www.csep.ca/pdfs/par-q.pdf.

16. Grundy SM, Cleeman JI, Merz CNB, et al. Coordinating Committee of the National Cholesterol Education Program. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation* 2004;110:227-239. Available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04.htm.

17. U.S. Department of Health and Human Services, U.S. Department of Agriculture. *Dietary Guidelines for Americans.* Washington, DC: U.S. Government Printing Office, 2005. Stock Number 001-000-04719-1. Available at http://www.healthierus.gov/dietaryguidelines/.

18. National Heart, Lung, and Blood Institute. The DASH Eating Plan. Updated May 2003. Bethesda, MD: National Institutes of Health, 2003. Available at http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/.

19. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 1995;273(5):402-407.

20. U.S. Department of Health and Human Services. *Physical Activity and Health: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, 1996. Available at http://www.cdc.gov/nccdphp/sgr/sgr.htm.

21. Task Force on Community Preventive Services. *Guide to Community Preventive Services. Systematic Reviews of Community Interventions to Increase Physical Activity.* Atlanta: Task Force on Community Preventive Services, 2002. Available at http://www.thecommunityguide.org/pa/default.htm.

22. Obesity Education Initiative. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* NIH Publication No. 98-4083. Bethesda, MD: National Heart, Lung, and Blood Institute, 1998. Available at http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm.

23. Obesity Education Initiative. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* Bethesda, MD: National Heart, Lung, and Blood Institute, 2000. Available at http://www.nhlbi.nih.gov/guidelines/obesity/practgde.htm.

24. Public Health Service. *Treating Tobacco Use and Dependence: A Systems Approach.* Clinical Practice Guideline. Atlanta: U.S. Department of Health and Human Services, 2000.

25. National Cholesterol Education Program. *ATP III Guidelines At A Glance Quick Desk Reference Guide.* NIH Publication No. 01-3305. Bethesda, MD: National Heart, Lung, and Blood Institute, 2001. Available at http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.pdf.

26. Treating Tobacco Use and Dependence—Clinician's Packet. A How-To Guide for Implementing the Public Health Service Clinical Practice Guideline. March 2003. U.S. Public Health Service. Available at http://www.surgeongeneral.gov/tobacco/clinpack.html.

27. CDC. Chapter 1. The role of quitlines in comprehensive tobacco control programs. In: *Telephone Quitlines: A Resources for Development, Implementation, and Evaluation.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004. Available at http://www.cdc.gov/tobacco/quitlines.htm.

28. Lichtenstein E, Glasgow RE, Lando HA, et al. Telephone counseling for smoking cessation: rationales and meta-analytic review of evidence. *Health Education Research* 1996;11(2):243–257.

29. Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, 2000.

30. Hopkins DP, Briss PA, Ricard CJ, et al. Reviews of evidence regarding interventions to reduce tobacco use and exposure to environmental tobacco smoke. *American Journal of Preventive Medicine* 2001;20(Suppl 2):16-66.

31. Stead LF, Lancaster T, Perera R. Telephone counseling for smoking Chichester, UK: John Wiley & Sons, Ltd, 2004.

32. University of North Carolina's (UNC's) Center for Health Promotion and Disease Prevention. *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program.* Chapel Hill, NC: UNC, 2001. Available at www.hpdp.unc.edu/wisewoman/.

Additional Resources

Preventing Heart Disease Among Women

American Heart Association Guidelines. *Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women.*
http://circ.ahajournals.org/cgi/reprint/109/5/672

Helping Women Understand Their Test Values (Know Your Numbers Materials)

National Heart, Lung, and Blood Institute, National High Blood Pressure Education Program, National High Blood Pressure Education Month campaign material for May 2005. *Prevent and Control America's High Blood Pressure: Mission Possible. Know Your Numbers.*
http://hin.nhlbi.nih.gov/mission/abouthbp/numbers.htm

National Heart, Lung, and Blood Institute, National Cholesterol Education Program. *High Blood Cholesterol—What You Need to Know.*
http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.pdf

American Heart Association. *What Are Healthy Levels of Cholesterol?*
http://www.americanheart.org/presenter.jhtml?identifier=183

National Institutes of Health, National Diabetes Education Program, Control Your Diabetes for Life Campaign. *If You Have Diabetes Know Your Blood Sugar Number.*
http://www.ndep.nih.gov/diabetes/pubs/KnowNumbers_Eng.pdf

4 Building a Successful Lifestyle Intervention

Chapter 4: Building a Successful Lifestyle Intervention

This chapter provides guidance to help your project build a successful lifestyle intervention that meets the objectives of the WISEWOMAN program. The first section of this chapter provides general information on selecting and developing the lifestyle intervention. The second section provides requirements on data collection and analysis that your project must follow. The third section covers recommendations from national guidelines on how to encourage people to eat heart-healthy foods, be more physically active, and quit smoking. These recommendations provide the foundation for building your lifestyle intervention.

The mission of WISEWOMAN is to provide low-income, underinsured, or uninsured women aged 40–64 years with the knowledge, skills, and opportunities needed to improve their diet, physical activity, and other life habits (e.g., live tobacco-free) and thus prevent, delay, or control cardiovascular and other chronic diseases.

To accomplish this mission, the WISEWOMAN program funds state or tribal health agencies to provide eligible women with lifestyle interventions (LSIs) that have been rigorously studied and proven effective in reducing cardiovascular disease (CVD) risk factors by targeting tobacco use, obesity, poor diet, and physical inactivity. These lifestyle interventions have been created or adapted and then standardized for use throughout the state or tribal organization. Staff are required to review the existing literature and select scientifically sound, culturally relevant LSIs that will be most effective for their populations. Thus, LSIs vary across—but not within—projects.

Standard vs. Enhanced Projects

Standard WISEWOMAN projects must select an intervention that has already been evaluated and determined to be effective in reducing CVD risk factors. We refer to these as evidence-based LSIs. Enhanced WISEWOMAN projects, however, are funded to test the effectiveness of an LSI. *See page 86 for more information.*

WISEWOMAN LSIs are low in cost, especially when compared with the cost of treating chronic diseases once they have developed, and these interventions pose minimal risks to women in the program. We know of no other program that has the potential of providing low-income, middle-aged women across the United States with the knowledge, skills, and opportunities to adopt and maintain a heart-healthy lifestyle. We target these four major risk factors:

Smoking. Tobacco use remains the leading preventable cause of death in the United States, causing approximately 440,000 deaths each year.[1] The long list of diseases caused by smoking includes CVDs, chronic lung diseases, and many different cancers (e.g., cervical, esophageal, lung, and oral cancers).[2]

Overweight and obesity. There is convincing evidence to support the benefit of weight loss for reducing high blood pressure, improving lipid levels, and lowering blood glucose. Being overweight or obese substantially increases the risk of morbidity from high blood pressure; high cholesterol; type 2 diabetes; coronary heart disease; stroke; osteoarthritis; and endometrial, breast, and colon cancers.[3]

Poor diet. Good nutrition is vital to good health. Diseases associated with unhealthy dietary behavior rank among the leading causes of illness and death in the United States. Major diseases in which diet plays a role include CVD, some types of cancer, stroke, obesity, osteoporosis, and type 2 diabetes.[4]

Physical inactivity. Regular physical activity substantially reduces a person's risk of dying of heart disease, the nation's leading cause of death. Moreover, being physically active decreases the risk for stroke, colon cancer, diabetes, and high blood pressure. Physical activity also helps control weight; contributes to healthy bones, muscles, and joints; reduces falls among older adults; helps relieve arthritis pain; and reduces the symptoms of anxiety and depression.[5]

Our Focus: Health Promotion and Primary Prevention

The aims of the WISEWOMAN LSI are to promote health and to prevent, delay, or control cardiovascular and other chronic disease risk factors. Therefore, all women in your project, regardless of their screening results, should be encouraged to attend the LSI and adopt healthy lifestyle habits. Your project should have systems in place to ensure that all women who have completed the risk factor screening are given opportunities to attend and complete the standardized LSI that your project has developed.

Because WISEWOMAN funds cannot be used to cover treatment, the program has determined that therapeutic interventions, such as medical nutrition therapy and diabetes self-management education cannot be supported with WISEWOMAN funds. However, through the LSI, WISEWOMAN promotes the importance of behaviors that can help women control their diabetes, including making healthy food choices, engaging in physical activity, and living tobacco-free.

Your LSI should be designed and implemented in a way that helps women meet or exceed the following behavioral goals within the first 12 months of participating in your WISEWOMAN project. Data are collected from each woman at the initial screening and again at the evaluation screening to determine if behavioral changes have been made.

- Achieve the recommended intake of fruits and vegetables each day while consuming the appropriate number of calories. For most women, this means increasing the servings of fruits and vegetables and reducing the amount of other foods that they consume. For example, a woman consuming 1,600 calories a day should eat 2 cups of vegetables and 1 1/2 cups of fruit.

The aims of the WISEWOMAN LSI are to promote health and to prevent, delay, or control cardiovascular and other chronic disease risk factors. Therefore, all women in your project, regardless of their screening results, should be encouraged to attend the LSI and adopt healthy lifestyle habits.

Policy on Diabetes-Specific Interventions

Diabetes-specific interventions, to include medical nutrition therapy, will not be reimbursed with WISEWOMAN funds. However, the time spent to identify resources for women with diabetes and to refer these women to diabetes-specific interventions can be supported by WISEWOMAN funds. The WISEWOMAN program recommends that projects identify affordable resources and provide referrals for women with diabetes.

Measuring Change in Behavior

The primary outcomes that your project will measure are blood pressure, lipid levels, body mass index (based on measured height and weight), tobacco use, and blood glucose. Intermediate outcomes that you will measure include changes in behavior (e.g., self-reported changes in diet and physical activity). Some projects also measure women's readiness for change and barriers to behavior change. They use this information to help women move forward so they can adopt and maintain healthy behaviors.

- Achieve or exceed the recommended number of minutes that participants spend each day in moderate physical activity. CDC/American College of Sports Medicine (ACSM) recommendations state that adults should engage in 30 minutes per day of moderate-intensity physical activity on most, preferably all, days of the week.
- Quit smoking, for women who smoke.

Selecting and Developing the Lifestyle Intervention

Your WISEWOMAN project coordinator and LSI specialist should work with your public health advisory committee to identify the LSI that best supports the goals of the WISEWOMAN program in your state or tribal organization.

Literature reviews, theoretical foundations, and training courses can help your project select and develop the appropriate LSI. These activities can help LSI planners determine who should deliver the LSI (e.g., nutritionists, community health workers); how the LSI sessions should be delivered; and when, where, and how often these LSI sessions should occur.

When you develop your LSI, also take into consideration the strategies needed to encourage women to participate in and complete the LSI, as well as the type of community linkages and support needed to help women maintain their healthy behaviors.

Emphasis Is on the First 12 Months of Participation in WISEWOMAN

Focusing on the first 12 months of a woman's participation in the project is critical to the success of the WISEWOMAN program. Women should complete the initial screening visit, the LSI, and the evaluation (first annual) screening visit. Data from each of these visits are captured during the first year and are analyzed to determine the impact of the program.

Literature Reviews

The independent Task Force on Community Preventive Services has worked with groups of experts to systematically review studies of population-based interventions focusing on physical activity and tobacco.[6] Similar reviews on nutrition will be added to the Task Force's *Guide to Community Preventive Services* in the near future. We encourage your project to incorporate the relevant recommendations of the *Community Guide* into your LSI.

The Agency for Healthcare Research and Quality (AHRQ) sponsored a literature review to update the chapter from the 1996 *Guide to Clinical Preventive Services* that examines the effectiveness of counseling in promoting a healthy diet.[7] The report concluded that diets low in saturated and trans fat and high in fruits, vegetables, fish, and whole grains are associated with better health outcomes. Counseling adults can improve dietary behaviors, including reductions in total and saturated fat intake and increases in fruit and vegetable consumption. They found that more intensive counseling and counseling directed to higher risk patients have generally produced larger changes than less intensive interventions delivered to low-risk populations. The report provides recommendations that could be relevant to WISEWOMAN projects that provide the LSI through primary care settings.

Counseling in a Primary Care Setting

Many WISEWOMAN projects use primary care staff, such as nurses, dietitians, or nutritionists, to deliver the LSI. If this is the case for your project, you may want to review the recommendations for behavioral counseling to promote a healthy diet found in the *Guide to Clinical Preventive Services,* which is available from the Agency for Healthcare Research and Quality (AHRQ) at www.preventiveservices.ahrq.gov.

Wilcox and colleagues (2001) conducted a literature review to identify effective nutrition and physical activity interventions in health care settings to reduce women's CVD risk (see Appendix K).[8] The authors determined the size of the effect of 32 interventions whose goal was to affect body mass index or weight, dietary fat, blood pressure, or total and low-density lipoprotein serum cholesterol. The more successful interventions were PACE (Patient-Centered Assessment & Counseling

for Exercise & Nutrition) and A New Leaf...Choices for Healthy Living. Both of these interventions are currently used by WISEWOMAN projects.

The Women's Cardiovascular Health Network, whose members represent 10 Prevention Research Centers, also conducted a literature review (see Appendix K).[9] They identified 65 population-based studies that focused on improving women's cardiovascular health by decreasing tobacco use, physical inactivity, and poor diet. Although few cardiovascular health interventions are geared toward women, the network did identify effective program components. These include personalized advice on diet, physical activity, and tobacco cessation; multiple staff contacts to build healthy behavior skills (e.g., how to order healthy foods when eating out, how to budget time for physical activity, how to use a pedometer); daily self-monitoring; and combinations of strategies. For more information about the Women's Cardiovascular Health Network, see http://www.hsc.wvu.edu/womens-cvh/.

Theoretical Foundations

Programs that are based on a clear understanding of the targeted health behaviors and their environmental context are most likely to succeed. Theories can help programs during the various stages of planning, implementing, and evaluating an intervention. Program planners use theories to help find answers to ***why? what?*** and ***how?*** For example, theories can be used to guide your search for

- **Why** women in your project are or are not following public health and medical advice or are not caring for themselves in healthy ways.
- **What** you need to know before developing or organizing an intervention program.
- **What** should be monitored, measured, or compared in the program evaluation.
- **How** your project can shape program strategies to reach people and organizations and help them make positive changes.[10]

There are many theories that are relevant to your LSI. To help you understand how your project's LSI can influence changes at many different levels and how these influences can interact, look at your project from the social ecological perspective. Although all eligible WISEWOMAN participants are offered interventions that address their individual problems, we encourage you to also work with your partners to address the various levels of influence identified through the social ecological perspective. Table 4.1 lists theories that might have been

used to develop the LSI you are providing. Knowing about these theories can help you better understand why certain steps are necessary to have a successful LSI.

Table 4.1. Social Ecological Perspective of Theories

Problem and Intervention Level	Theories
Individual	• Theory of planned behavior • Transtheoretical model (stage of change) • Persuasion communication model • Goal-setting theory • Attribution theory • Health belief model • Self-regulation theories
Interpersonal	• Social cognitive theory • Diffusion of innovations theory • Social network and social support theories
Organization	• Stage theory of organizational change • Organizational development theory • Interorganizational relationship theory
Community	• Community organization
Society and Policy	• Agenda-building theory • Policy windows theory

Source: *Intervention Mapping,* 2001, p.80.

For more information about theoretical foundations, see the National Cancer Institute's publication *Theory At A Glance* at http://www.cancer.gov/aboutnci/oc/theory-at-a-glance/allpages.[10] WISEWOMAN provides training on behavioral change models and theories through the Nutrition and Public Health course, described in the next section.

Training Courses

Nutrition and Public Health: A Course for Community Practitioners

The WISEWOMAN-sponsored course on nutrition and public health provides technical assistance to help projects develop, implement, and evaluate the nutrition component of their LSI. This course was developed for public health practitioners with limited experience in nutrition science or behavioral interventions who work with populations with little

or no access to health care services. Emphasis is given to nutrition interventions for low-income and minority women at increased risk for chronic diseases associated with dietary and lifestyle practices. Faculty with practical or academic expertise will teach public health approaches for promoting healthy eating through interventions designed to produce changes at the individual, community, and environmental/policy levels. Topics for the course include

- Hot topics in nutrition science.
- Social ecologic and public health practice models for nutrition promotion.
- Needs and assets assessment—individual and community.
- Intrapersonal and interpersonal behavioral change.
- Organization and community influences on diet and strategies for change.
- Policies that affect dietary intake and their potential to influence change.
- Program evaluation.
- Development of plain language materials for low-literacy, low-income, and culturally diverse audiences.
- Examples of exemplary nutrition programs.

This course will be offered annually, and attendance is mandatory for key WISEWOMAN project staff (i.e., project coordinator and intervention specialist). For more information about the course, see http://www.hpdp.unc.edu/nph/.

Physical Activity and Public Health Course

WISEWOMAN funds may be used to send staff to the Physical Activity and Public Health (PAPH) Course, which is co-sponsored by CDC and the University of South Carolina Prevention Research Center. The PAPH course has two tracks: one for practitioners and one for researchers. More information about the two-track course can be found at http://prevention.sph.sc.edu/seapines/.

The 6-day practitioner course was developed for personnel who are involved or interested in community-based initiatives to promote physical activity. Topics for the course include

- Public health models for physical activity promotion.
- Epidemiology/needs assessment.
- "Best practice" intervention strategies.
- Policy and environmental supports for physical activity.
- Program evaluation.
- Partnership development.
- Current research on physical activity promotion.

The course is taught by nationally known public health practitioners and researchers and emphasizes one-on-one and small-group interaction with these experts.

The 8-day course for post-doctoral researchers is designed to develop research competencies related to physical activity and public health. Topics include grantsmanship skills; research funding opportunities; measurement of physical activity; design of epidemiologic studies; dose-response issues; individual, community, and policy interventions; critical research needs related to physical activity in women, minorities, and youth; and numerous special topics. Instructional techniques include lectures, small-group discussions, individual meetings with faculty, and individual grant-writing projects.

Community Engagement

As you plan your LSI, consider how important community engagement will be to your project's success. By engaging the community and developing partnerships, your project can help bring about the systemic changes needed to sustain your efforts to promote cardiovascular health among underserved women.

The CDC/ATSDR Committee for Community Engagement defines *community engagement* as the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interests, or similar situations to address issues affecting the well-being of community members. Community involvement is a powerful vehicle for bringing about environmental and behavioral changes that improve the health of community members, including WISEWOMAN participants. It often involves partnerships and coalitions that help mobilize resources, influence systems, and serve as catalysts for changing policies, programs, and practices. For more on this subject, refer to the

Principles of Community Engagement (available at http://www.cdc.gov/phppo/pce/index.htm).[11]

Getting Approval for the Intervention Your Project Has Selected

Once you have identified your LSI, you must describe your intervention plan in the form of a protocol. Both enhanced and standard projects are required to submit a protocol to CDC for approval.

- **Enhanced Projects.** Enhanced WISEWOMAN projects are funded to use scientifically rigorous methods to test the effectiveness of a behavioral or LSI aimed at preventing CVD. Enhanced projects must submit intervention plans in the form of a protocol for CDC project officer approval. They should also work with their CDC project officer to determine if CDC's Institutional Review Board should be involved. Enhanced projects are strongly encouraged to use the expertise of their state or local academic community or other academic communities already involved in WISEWOMAN projects.

- **Standard Projects.** Standard WISEWOMAN projects are funded to provide an evidence-based and culturally appropriate LSI. Standard projects must select an intervention that has been scientifically shown to be effective in lowering blood pressure or cholesterol or improving physical activity or nutrition in a target population similar to that of WISEWOMAN. The intervention should incorporate sound theoretical principles of behavioral change. These principles include use of the social ecologic model to intervene at multiple levels, individual tailoring, self-efficacy, self-monitoring and reinforcement, readiness for change, small achievable steps, social support, collaborative goal-setting, and strategies to overcome barriers.

While developing your LSI plan, we encourage all projects—enhanced and standard—to use a systematic team approach that involves health care professionals and paraprofessionals, community health workers, and community resources. A team is necessary to provide the education, follow-up, and support that WISEWOMAN participants need to adopt and sustain behavioral change.

Protocol Describing Your Lifestyle Intervention Plan

In accordance with the Protocol Requirements described in Chapter 2, you will need to develop a protocol describing your LSI plan and submit this protocol to your CDC project officer for approval before you begin the screening and intervention. In addition, if your project is an enhanced project (i.e., is required to conduct research), you will need to work with your CDC project officer to determine what procedure will be needed for Institutional Review Board approval. Changes in LSI protocol will require justification and the approval of your CDC project officer. This applies to both standard and enhanced WISEWOMAN projects.

Lifestyle Intervention Management

As you develop your LSI, you must plan how you will encourage women to participate in your intervention and stick with the program. This is what we refer to as ***lifestyle intervention management—***all services provided outside your formal intervention program to encourage women to attend intervention sessions and adhere to LSIs. You may use WISEWOMAN funds to provide these management services. For example, you could pay for community health workers to make telephone calls that remind and encourage women to attend an LSI session or ask the women about progress they have made in achieving their behavioral goals.

Policy on Lifestyle Intervention Management

You may use WISEWOMAN funds to provide management and support services to promote complete attendance at and adherence to your project's standardized lifestyle intervention program:

- Standard projects must ensure that 75% of newly enrolled women who have completed baseline screening attend at least one lifestyle intervention session and that 60% attend all intervention sessions.
- Enhanced projects must ensure that at least 75% of newly enrolled women who have completed baseline screening in the intervention group complete all lifestyle intervention sessions.

Should Women Repeat the LSI?

We encourage you to place a high priority on providing the LSI to women who are newly screened and to women who have not previously attended the LSI. If you determine that a particular woman would greatly benefit from attending the LSI for a second time, this could be allowed if resources are adequate to support it.

As mentioned previously, all women—regardless of screening results—should be encouraged to participate in the LSI. Your project will need to identify capacity-building strategies that will help you meet this expectation and the program's LSI performance standards (i.e., 75% of newly enrolled women complete at least one LSI session and 60% complete all LSI sessions). Some currently funded projects are working with university outreach and extension specialists or other trained staff across their state/organization to provide group LSI sessions. Others provide LSI group or individual sessions in the evenings and on weekends. The majority of currently funded projects allow some or all of their LSI sessions to be conducted over the telephone. The following guidance is provided to help you identify what counts as an LSI session.

At a minimum, the LSI session should

1. Facilitate the adoption of health-promoting behavior (including healthful eating, physical activity, and/or tobacco cessation) ***and***
2. Be provided by an interventionist who has completed training on the project's standardized LSI ***and***
3. Include goal setting, problem solving, and/or skill or knowledge building ***and***
4. Use standardized materials that contain messages that are in line with national guideline recommendations. Furthermore, the key messages shared with participants should be consistent from one interventionist to another throughout the project ***and***
5. Be at least 15 minutes in length (if conducted one on one) ***or***
6. Be at least 30 minutes in length (if conducted in a group setting).

Maintenance or Relapse Prevention Programs

Although LSI programs are intended to help individuals quit tobacco use and adopt positive dietary and physical activity behaviors, surprisingly few of these programs result in long-lasting change. Programs that do not achieve long-term behavioral change cannot be considered highly effective, and they do not make efficient use of health facility resources. The high rates of relapse that tend to occur after short-term behavioral interventions require us to establish *maintenance* programs that promote long-term adherence to the new behavioral patterns. We encourage WISEWOMAN projects to identify community partners and provide participants with linkages to low-cost community resources that support their goals. In addition, the North Carolina WISEWOMAN

Help Her Maintain Positive Behaviors

To promote long-term adherence to new behavioral patterns, we encourage WISEWOMAN projects to identify community partners and provide participants with linkages to low-cost community resources that support their goals.

manual, *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program,*[12] developed by the Center for Health Promotion and Disease Prevention at the University of North Carolina at Chapel Hill, states that well-designed maintenance programs should have the following characteristics:

- Provide the participant with ongoing contact with health facility staff (either in person or by mail).
- Are cost-effective and time-efficient.
- Involve the participant in collaborative planning (including goal-setting) and development of a treatment plan.
- Include relapse prevention strategies that incorporate rewards, helping relationships, counter-conditioning, and stimulus control.

Data Requirements for Tracking Lifestyle Intervention Attendance

In addition to collecting data that will allow you to determine if behavioral changes have occurred, you will also be required to track each woman's participation in the intervention sessions. CDC needs this information to ensure that women enrolled in your LSI receive the complete intervention program, to determine whether the activities are completed in a timely manner, and to evaluate the WISEWOMAN program's impact. Minimum data elements (MDEs) that you must report twice a year include

- The date of the session attended.
- The type of intervention session (i.e., nutrition, physical activity, tobacco, or a combination).
- The setting (e.g., individual or group, face to face, or over the telephone).

These MDEs will be extremely useful to you. We encourage you to use this information to identify barriers that hinder your intervention's effectiveness and to take steps to overcome these barriers. In addition, we strongly encourage your project to collect data above and beyond the MDEs required by the WISEWOMAN program. This additional information can help you continually identify areas for improvement.

For more ideas about evaluation, please see Chapter 5.

Policy on Tracking Participation in Lifestyle Interventions

Projects will develop a system for analyzing participant data to ensure that a woman enrolled in the lifestyle intervention receives the complete intervention program in a timely manner and to assist with program evaluation.

Recommendations from National Guidelines

To guide you as you develop your LSI, refer to the recommendations from national guidelines for heart-healthy eating, increased physical activity, and tobacco cessation. A summary of these recommendations is provided throughout this chapter.

Recommendations on Diet

Which Dietary Recommendations Should be Used?

Your LSI should incorporate dietary recommendations that are consistent with the 2005 *Dietary Guidelines for Americans.* You might notice that there are some differences between the dietary recommendations in the APT III's therapeutic lifestyle changes or TLC diet (emphasis is on lowering LDL cholesterol) and JNC 7's DASH (Dietary Approaches to Stop Hypertension) Eating Plan (emphasis is on preventing and managing hypertension). However, the overall composition of the TLC diet and the DASH Eating Plan are both consistent with the recommendations from the *Dietary Guidelines for Americans.* Therefore, the LSI you select can use recommendations from either of these resources.

Dietary Guidelines for Americans

The *Dietary Guidelines for Americans* is published jointly every 5 years by the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA).[4] These guidelines provide authoritative advice about how good dietary habits can promote health and reduce risk for major chronic diseases among people 2 years of age or older. These guidelines provide science-based advice to promote health and to reduce the risk for major chronic diseases through diet and physical activity. Two examples of eating patterns that follow the Dietary Guidelines are

- The DASH (Dietary Approaches to Stop Hypertension) Eating Plan (http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/).[13]
- USDA Food Guide, which is the basis for USDA's MyPyramid (www.MyPyramid.gov).[14]

The key messages most relevant to WISEWOMAN are summarized below. More information about the Dietary Guidelines can be found at http://www.healthierus.gov/dietaryguidelines/.

For more information about the 2005 Dietary Guidelines for Americans, *the DASH Eating Plan, the USDA's MyPyramid food guidance system, and other dietary recommendations, see the Additional Resources section at the end of this chapter.*

Key Recommendations from the 2005 Dietary Guidelines for Americans

ADEQUATE NUTRIENTS WITHIN CALORIE NEEDS

- Consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and trans fats, cholesterol, added sugars, salt, and alcohol.
- Meet recommended intakes within energy needs by adopting a balanced eating pattern, such as the U.S. Department of Agriculture (USDA) Food Guide or the Dietary Approaches to Stop Hypertension (DASH) Eating Plan.

Key Recommendations for Specific Population Groups*

People older than age 50. Consume vitamin B12 in its crystalline form (i.e., fortified foods or supplements).

✧ *Older adults, people with dark skin, and people exposed to insufficient ultraviolet band radiation (i.e., sunlight).* Consume extra vitamin D from vitamin D-fortified foods and/or supplements.

WEIGHT MANAGEMENT

- To maintain body weight in a healthy range, balance calories from foods and beverages with calories expended.
- To prevent gradual weight gain over time, make small decreases in food and beverage calories and increase physical activity.

Key Recommendations for Specific Population Groups*

Those who need to lose weight. Aim for a slow, steady weight loss by decreasing calorie intake while maintaining an adequate nutrient intake and increasing physical activity.

✧ *Overweight adults and overweight children with chronic diseases and/or on medication.* Consult a health care provider about weight-loss strategies prior to starting a weight-reduction program to ensure appropriate management of other health conditions.

PHYSICAL ACTIVITY

- Engage in regular physical activity and reduce sedentary activities to promote health, psychological well-being, and a healthy body weight.

- ✧ To reduce the risk of chronic disease in adulthood: Engage in at least 30 minutes of moderate-intensity physical activity, above usual activity, at work or home on most days of the week.
- ✧ For most people, greater health benefits can be obtained by engaging in physical activity of more vigorous intensity or longer duration.
- ✧ To help manage body weight and prevent gradual, unhealthy body weight gain in adulthood: Engage in approximately 60 minutes of moderate- to vigorous-intensity activity on most days of the week while not exceeding caloric intake requirements.
- ✧ To sustain weight loss in adulthood: Participate in at least 60 to 90 minutes of daily moderate-intensity physical activity while not exceeding caloric intake requirements. Some people may need to consult with a health care provider before participating in this level of activity.

- Achieve physical fitness by including cardiovascular conditioning, stretching exercises for flexibility, and resistance exercises or calisthenics for muscle strength and endurance.

Key Recommendations for Specific Population Groups*

Older adults. Participate in regular physical activity to reduce functional declines associated with aging and to achieve the other benefits of physical activity identified for all adults.

FOOD GROUPS TO ENCOURAGE

- Consume a sufficient amount of fruits and vegetables while staying within energy needs. Two cups of fruit and 2½ cups of vegetables per day are recommended for a reference 2,000-calorie intake, with higher or lower amounts depending on the calorie level.
- Choose a variety of fruits and vegetables each day. In particular, select from all five vegetable subgroups (dark green, orange, legumes, starchy vegetables, and other vegetables) several times a week.
- Consume 3 or more ounce-equivalents of whole-grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products. In general, at least half the grains should come from whole grains.
- Consume 3 cups per day of fat-free or low-fat milk or equivalent milk products.

FATS

- Consume less than 10 percent of calories from saturated fatty acids and less than 300 mg/day of cholesterol, and keep trans fatty acid consumption as low as possible.

- Keep total fat intake between 20% and 35% of calories, with most fats coming from sources of poly-unsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.
- When selecting and preparing meat, poultry, dry beans, and milk or milk products, make choices that are lean, low-fat, or fat-free.
- Limit intake of fats and oils high in saturated and/or trans fatty acids, and choose products low in such fats and oils.

CARBOHYDRATES

- Choose fiber-rich fruits, vegetables, and whole grains often.
- Choose and prepare foods and beverages with little added sugars or caloric sweeteners. (See amounts of sweeteners suggested by the USDA Food Guide and the DASH Eating Plan.)
- Reduce the incidence of dental caries by practicing good oral hygiene and consuming sugar- and starch-containing foods and beverages less frequently.

SODIUM AND POTASSIUM

- Consume less than 2,300 mg of sodium (approximately 1 teaspoon of salt) per day.
- Choose and prepare foods with little salt. At the same time, consume potassium-rich foods, such as fruits and vegetables.

Key Recommendations for Specific Population Groups

Individuals with hypertension, blacks, and middle-aged and older adults. Aim to consume no more than 1,500 mg of sodium per day, and meet the potassium recommendation (4,700 mg/day) with food.

ALCOHOLIC BEVERAGES

- Those who choose to drink alcoholic beverages should do so sensibly and in moderation—defined as the consumption of up to one drink per day for women and up to two drinks per day for men.

- Alcoholic beverages should not be consumed by some individuals, including those who cannot restrict their alcohol intake, women of childbearing age who may become pregnant, pregnant and lactating women, children and adolescents, individuals taking medications that can interact with alcohol, and those with specific medical conditions.
- Alcoholic beverages should be avoided by individuals engaging in activities that require attention, skill, or coordination, such as driving or operating machinery.

FOOD SAFETY

- To avoid microbial food borne illness:
  - ✧ Clean hands, food contact surfaces, and fruits and vegetables. Meat and poultry should not be washed or rinsed.
  - ✧ Separate raw, cooked, and ready-to-eat foods while shopping, preparing, or storing foods.
  - ✧ Cook foods to a safe temperature to kill microorganisms.
  - ✧ Chill (refrigerate) perishable food promptly and defrost foods properly.
  - ✧ Avoid raw (unpasteurized) milk or any products made from unpasteurized milk, raw or partially cooked eggs or foods containing raw eggs, raw or undercooked meat and poultry, unpasteurized juices, and raw sprouts.

Key Recommendations for Specific Population Groups

- *Infants and young children, pregnant women, older adults, and those who are immunocompromised.* Do not eat or drink raw (unpasteurized) milk or any products made from unpasteurized milk, raw or partially cooked eggs or foods containing raw eggs, raw or undercooked meat and poultry, raw or undercooked fish or shellfish, unpasteurized juices, and raw sprouts.
- *Pregnant women, older adults, and those who are immunocompromised.* Only eat certain deli meats and frankfurters that have been reheated to steaming hot.

* Only those key recommendations for specific population groups relevant to WISEWOMAN were included.

ATP III

The *Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults: Adult Treatment Panel III* (ATP III)[15] recommends therapeutic lifestyle changes (TLC) to lower LDL cholesterol and reduce the risk for CVD. Features of TLC are weight management, increased physical activity, and dietary modifications. The TLC diet encourages

- Eating foods that are low in saturated fat, trans fats, and cholesterol and those rich in complex carbohydrates and fiber, such as whole grains, fruits, and vegetables.
- Balancing energy intake with energy expenditure to maintain a desirable body weight or to prevent weight gain.

The overall composition of the TLC diet is consistent with the recommendations from the *Dietary Guidelines for Americans.* For more information about the TLC diet, see http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3_rpt.pdf.

Although achieving and maintaining normal body weight is the ideal goal, losing as little as 10 pounds reduces blood pressure and prevents hypertension in a large proportion of overweight adults.

JNC 7

The *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7)[16] states that adopting a healthy lifestyle is critical for preventing high blood pressure and managing hypertension. Although achieving and maintaining normal body weight is the ideal goal, losing as little as 10 pounds reduces blood pressure and prevents hypertension in a large proportion of overweight adults. To reduce blood pressure, JNC 7 recommends that adults follow DASH Eating Plan, which is rich in fruits, vegetables, and low-fat dairy products (http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/new_dash.pdf).[13] JNC 7 also recommends reducing dietary sodium and limiting alcohol intake.

The report states that combining two or more lifestyle changes can lead to even better results and therefore recommends that everyone who is able should engage in regular aerobic physical activity, and that people who smoke should be strongly counseled to quit smoking. Table 4.2 provides a summary of these lifestyle modifications and the impact they have on blood pressure. For more about preventing and managing high blood pressure, see http://www.nhlbi.nih.gov/guidelines/hypertension/.

Table 4.2. Lifestyle Modifications to Prevent and Manage Hypertension*—JNC 7[16]

Modification	Recommendation	Approximate SBP Reduction (Range)†
Weight reduction	Maintain normal body weight (body mass index 18.5–24.9 kg/m^2).	5–20 mm Hg/10 kg
Adopt DASH Eating Plan	Consume a diet rich in fruits, vegetables, and low-fat dairy products with a reduced content of saturated and total fat.	8–14 mm Hg
Reduce dietary sodium	Reduce dietary sodium intake to no more than 2.4 g (2,400 mg) sodium or 6 g salt.	2–8 mm Hg
Engage in regular physical activity	Engage in regular aerobic physical activity, such as brisk walking, for at least 30 minutes per day, most days of the week.	4–9 mm Hg
Drink alcohol only in moderation	Limit consumption to no more than 1 drink per day for women.	2–4 mm Hg

* For overall cardiovascular risk reduction, stop smoking.

† The effects of implementing these modifications are dose- and time-dependent and could be greater for some individuals.

Sustained Lifestyle Changes Cut Risk for Diabetes

Studies suggest that the progression from prediabetes to diabetes can be prevented or delayed. In 2001, results from two landmark clinical trials—the Finnish Diabetes Prevention Study and the U.S. Diabetes Prevention Program (DPP)—demonstrated that sustained lifestyle changes that included modest weight loss and physical activity substantially reduced progression to diabetes among older adults who were at very high risk. Results from the DPP were so compelling that the trial was ended a year early. The LSI worked equally well for men and women and all racial and ethnic groups. A healthy diet and modest physical activity can help people cut their risk for type 2 diabetes.[17]

The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

The Practical Guide was developed by the North American Association for the Study of Obesity and the National Heart, Lung, and Blood Institute (NHLBI).[3] It is based on the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Evidence Report* developed by the NHLBI Expert Panel. The low-calorie Step 1 diet recommended by *The Practical Guide* is similar to the DASH diet and the Dietary Guidelines except for its focus on reducing calories to lose weight. To help overweight people adjust to a low-calorie diet, the guide also recommends dietary education that includes information on the energy value of foods, food composition and caloric content, nutrition labels, food preparation, and portion sizes. For more information, see http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm.

Guide to Community Preventive Services

The independent Task Force on Community Preventive Services, developer of the *Guide to Community Preventive Services,*[6] is working with a group of experts to conduct a systematic review of studies of population-based interventions focusing on several nutrition areas that pertain to the WISEWOMAN program: community approaches for increasing fruit and vegetable intake; food and beverage availability; and price, portion size, and labeling in restaurants.

The WISEWOMAN program will provide your project with additional information on these resources as they become available. For more information about the task force's recommendations on nutrition interventions, see http://www.thecommunityguide.org. For information about the task force's review of healthy-weight interventions, see http://www.thecommunityguide.org/obese/obese.pdf.

DASH Eating Plan

As previously noted, both the *Dietary Guidelines for Americans* and the JNC 7 encourage people to follow the DASH Eating Plan, which is rich in vegetables, fruits, and low-fat dairy products and low in total and saturated fat. The DASH Eating Plan is also low in cholesterol; high in

dietary fiber, potassium, calcium, and magnesium; and moderately high in protein. The DASH-Sodium trial found that diet along with sodium restriction is beneficial for preventing and controlling high blood pressure.[18] In addition, people with high blood cholesterol may also benefit from this eating plan.[19] For more information about the DASH diet, see http://www.nhlbi.nih.gov/hbp/prevent/h_eating/h_eating.htm.

5 A Day—Eat a Variety of Colorful Fruits and Vegetables Every Day

Consuming a diet rich in fruits and vegetables may reduce a person's risk for cancer and other chronic diseases. Fruits and vegetables provide essential vitamins and minerals, fiber, and other substances that are important for good health. Most fruits and vegetables are naturally low in fat and calories and are filling. *5 A Day—Eat a Variety of Colorful Fruits and Vegetables Every Day* is a national program and partnership that seeks to increase the number of daily servings of fruits and vegetables Americans eat to five or more. Each state has a 5 A Day program coordinator who can assist WISEWOMAN projects in developing ways to help participants change their daily eating patterns to include more fruits and vegetables. For more about CDC's 5 A Day program, see http://www.cdc.gov/5aday/.[20]

Although the recommendations from the following national sources vary somewhat, they all advise adults to have at least 30 minutes of moderate-intensity physical activity on most, preferably all, days of the week.

Recommendations on Physical Activity

Surgeon General's Report

LSI counseling geared toward physical activity should support recommendations from the *Surgeon General's Report on Physical Activity and Health.*[5] These recommendations advise people of all ages to have at least 30 minutes of physical activity of moderate intensity (such as brisk walking) on most, preferably all, days of the week. The report also acknowledges that most people can obtain greater health benefits by engaging in physical activity of more vigorous intensity or of longer duration. The report can be downloaded from http://www.cdc.gov/nccdphp/sgr/contents.htm.

Previously sedentary women who begin physical activity programs should start with short intervals (5–10 minutes) of physical activity and gradually build up to the desired level of activity.[5]

Chapter 3 contains information about referring and clearing women to participate in the physical activity portion of the LSI.

The 10-Minute Bout

"The barrier often given for a failure to be physically active is lack of time. Setting aside 30 to 60 consecutive minutes each day for planned exercise is one way to obtain physical activity, but it is not the only way. Physical activity may include short bouts (e.g., 10-minute bouts) of moderate-intensity activity. The accumulated total is what is important—both for health and for burning calories. Physical activity can be accumulated through three to six 10-minute bouts over the course of a day."

—Dietary Guidelines for Americans[4]

CDC/ACSM

CDC/ACSM recommends that all adults should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferably all, days of the week.[21]

Guide to Community Preventive Services

In the *Guide to Community Preventive Services,* the Task Force on Community Preventive Services has released evidence-based recommendations on effective population-level interventions to promote physical activity.[6] An in-depth review of the evidence and recommendations, including information about how the reviews were conducted and commentaries from leading subject matter experts, was published in the May 2002 supplement to the *American Journal of Preventive Medicine.*[22] For more information see http://www.thecommunityguide.org.

Table 4.3. How Strategies Strongly Recommended by the Task Force on Community Preventive Services Are Relevant to WISEWOMAN Efforts to Promote Physical Activity

Strategy	Relevance to WISEWOMAN
Individually adapted behavior change programs. These programs are tailored to a person's specific interests or readiness to make a change in physical activity habits. Teaching people behavioral skills such as goal setting, building social support, self-rewards, problem solving, and relapse prevention helps them incorporate physical activity into their daily routines.	***Extremely relevant!***
Social support interventions in community contexts. The goal of this approach is to increase physical activity by creating or strengthening social networks. Examples include establishing an exercise buddy program, exercise contracts, and walking groups.	***Extremely relevant!*** WISEWOMAN staff are encouraged to incorporate social support into their lifestyle intervention.
Community-wide campaigns. These large-scale, highly visible, multicomponent campaigns direct their messages to large audiences by using a variety of approaches, including television, radio, newspapers, movie theaters, billboards, and mailings.	***Relevant.*** However, WISEWOMAN staff should work with partners to accomplish this.
Creating or improving access to places for physical activity, combined with information outreach. This approach ensures that the physical environment is conducive to physical activity by increasing the availability, accessibility, and acceptability of places where people can be physically active. Examples include building or improving the attractiveness of sidewalks, making stairwells safer and more inviting, and establishing walking or biking trails and exercise facilities in communities or in the workplace. By including information outreach, this approach strives to make people aware of available resources, encourage them to take local action, and help ensure that resources are well used.	***Relevant.*** However, WISEWOMAN staff are encouraged to work with partners to accomplish this.

Recommendations on Tobacco Use

Surgeon General's Reports

These recently published Surgeon General's reports are effective tools you can use to educate women about the harmful health effects of smoking and discuss ways to reduce tobacco use:

2004 *The Health Consequences of Smoking: A Report of the Surgeon General*[23]

2001 *Women and Smoking: A Report of the Surgeon General*[24]

2000 *Reducing Tobacco Use: A Report of the Surgeon General*[2]

All three reports are available at http://www.cdc.gov/tobacco/sgr/index.htm.

We encourage your project to assess provider referrals to the quitline and work with state tobacco control or quitline staff to identify how many WISEWOMAN participants have used this resource.

There is now a national TELEPHONE quitline at 1-800-QUITNOW (1-800-784-8669) or TTY, 1-800-332-8615, or on the Internet at http://www.smokefree.gov/.

Intensify Your Tobacco-Cessation Efforts

The more intense the counseling to reduce tobacco dependence, the greater the effectiveness. Work closely with your tobacco control partners to optimize resources and strategies to ensure that effective tobacco cessation programs are available to all of your WISEWOMAN participants.

Guide to Community Preventive Services

In the *Guide to Community Preventive Services,* the Task Force on Community Preventive Services addresses the effectiveness of community-based interventions within three strategic areas of tobacco use prevention and control: (1) preventing people from beginning to use tobacco products, (2) increasing the number of people who quit using tobacco, and (3) reducing exposure to secondhand smoke.[6] The *Community Guide* lists several strategies that have been proven effective. The WISEWOMAN program encourages projects to work with partners to carry out these recommended multicomponent strategies to help women quit using tobacco:

- **Patient reminder systems.** Projects can easily establish patient reminder systems by putting "current," "former," or "never" stickers on patients' charts to prompt providers to advise about quitting or support a person who has recently quit or never smoked.
- **Telephone counseling.** Many providers do not have the time to provide a thorough counseling session about the health risks of tobacco use. Most states currently have quitline services. Projects should consider developing a relationship with the state quitline to obtain counseling services for clients. Projects should also strongly consider developing a fax referral form that contains the client's consent to counseling. The project can fax this referral form directly to the quitline, and the quitline counselor can then call the client directly (this method is often referred to as a proactive quitline). Proactive telephone counseling is effective, several meta-analyses have found.[26–30] The current *U.S. Public Health Clinical Practice Guideline*[25] and the *Guide to Community Preventive Services*[6] both recommend proactive telephone counseling as a method to help smokers quit.[28–29] Proactive quitlines might provide some form of immediate reactive assistance when a tobacco user first calls, but they also provide more comprehensive services through outbound

(proactive) calls. The outbound service, which often entails multiple follow-up sessions, is typically scheduled by agreement with the smoker. Randomized, controlled trials have established the efficacy of such proactive interventions, with the most recent meta-analysis of 13 studies showing a 56% increase in quit rates when compared with self-help.[30]

- **Reducing out-of-pocket costs for participants.** Approximately 10 state quitlines provide free over-the-counter nicotine replacement medications to clients engaged in counseling. The availability of medications should be part of the partnership discussions with quitlines. Some state quitlines have reserved medications for uninsured and underinsured clients.

Recommendations from the document Treating Tobacco Use and Dependence: Public Health Service Clinical Practice Guideline[25] *can be found in Chapter 3.*

Table 4.4. How Strategies Strongly Recommended by the Task Force on Community Preventive Services Are Relevant to WISEWOMAN Efforts to Increase the Number of Women Who Quit Using Tobacco

Strategy	Relevance to WISEWOMAN
Telephone support with interventions* for people trying to quit. Provides information and motivation to tobacco product users through telephone contact.	***Extremely Relevant!*** Projects are encouraged to ensure that clients have access to quitlines.
Reducing participants' costs for treatments. Reduces or eliminates participant co-payments for effective cessation therapies.	***Relevant.*** However, WISEWOMAN funds may not be used for treatment.
Media campaigns with interventions.* Informs viewers of the health risks of tobacco use through long-term, high-intensity counter-advertising campaigns.	***Relevant.*** However, projects should work with partners to accomplish this.
Increasing the unit price for tobacco products. Increases the excise tax on cigarettes through government legislation.	WISEWOMAN will rely on other tobacco control programs to address this.

* Examples of interventions include distribution of materials about quitting, formal individual or group counseling, or nicotine replacement therapies (including patches or gum).

References

1. CDC. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 1997–2001. *MMWR* 2005;54(25):625–628.

2. U.S. Department of Health and Human Services. *Reducing Tobacco Use: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2000. Available at http://www.cdc.gov/tobacco/sgr/sgr_2000/index.htm.

3. National Heart, Lung, and Blood Institute and North American Association for the Study of Obesity. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* Bethesda, MD: National Institutes of Health, 2000. NIH Publication Number 00-4084. Available at http://www.nhlbi.nih.gov/guidelines/obesity/practgde.htm.

4. U.S. Department of Health and Human Services and U.S. Department of Agriculture. *Dietary Guidelines for Americans.* Washington, DC: U.S. Government Printing Office, 2005. Stock Number 001-000-04719-1. Available at http://www.healthierus.gov/dietaryguidelines/.

5. U.S. Department of Health and Human Services. *Physical Activity and Health: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, 1996. Available at http://www.cdc.gov/nccdphp/sgr/sgr.htm.

6. Task Force on Community Preventive Services. *Guide to Community Preventive Services.* Available at http://www.thecommunityguide.org/.

7. AHRQ counseling to promote a healthy diet. In: *Guide to Clinical Preventive Services.* 3rd edition. Systematic Evidence Reviews. Available at http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat3.chapter.3509.

8. Wilcox S, Parra-Medina D, Thompson-Robinson M, Will J. Nutrition and physical activity interventions to reduce cardiovascular disease risk in health care settings: a quantitative review with a focus on women. *Nutrition Reviews* 2001;59(7):197–214.

9. Krummel DA, Matson Koffman D, Bronner Y, et al. Cardiovascular health interventions in women: what works? *Journal of Women's Health and Gender-Based Medicine* 2001;10(2):117–136.

10. National Cancer Institute (NCI). *Theory At A Glance: A Guide for Health Promotion Practice.* Bethesda, MD: NCI, 2003. Available at http://www.nci.nih.gov/aboutnci/oc/theory-at-a-glance.

11. CDC. *Principles of Community Engagement.* Atlanta: CDC, 1997. Available at http://www.cdc.gov/phppo/pce/index.htm.

12. Center for Health Promotion and Disease Prevention, The University of North Carolina (UNC) at Chapel Hill. *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program.* Chapel Hill, NC: UNC, 2001. Available at www.hpdp.unc.edu/wisewoman/.

13. National Heart, Lung, and Blood Institute. *DASH—Dietary Approaches to Stop Hypertension.* Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, 2003. Available at http://www.nhlbi.nih.gov/hbp/prevent/h_eating/h_eating.htm.

14. U.S. Department of Agriculture. *MyPyramid.* Washington, DC: U.S. Department of Agriculture, 2005. Available at http://mypyramid.gov.

15. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *Executive Summary of the Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III).* NIH Publication No. 01-3670. Bethesda, MD: National Heart, Lung, and Blood Institute, 2001. Available at http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm.

16. Joint National Committee. *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (JNC 7). NIH Pub. No. 04-5230. Bethesda, MD: National Heart, Lung, and Blood Institute, 2004. Available at http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.htm.

17. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or Metformin. *New England Journal of Medicine* 2002;346(6):393–403.

18. Sacks FM, Svetkey, LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) Diet. *New England Journal of Medicine* 2001;344:3–10.

19. Obarzanek E, Sacks FM, Vollmer WM, et al. Effects on blood lipids of a blood pressure—lowering diet: the Dietary Approaches to Stop Hypertension (DASH) Trial. *American Journal of Clinical Nutrition* 2001;74(1):80–89.

20. CDC. 5 A Day—Eat a Variety of Colorful Fruits and Vegetables Every Day. Atlanta: CDC. Available at http://www.cdc.gov/5ADay.

21. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 1995;273(5):402–407.

22. Task Force on Community Preventive Services. Recommendations to increase physical activity in communities. *American Journal of Preventive Medicine* 2002;22 (Suppl 4):67–72.

23. U.S. Department of Health and Human Services. *The Health Consequences of Smoking: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004. Available at http://www.cdc.gov/tobacco/sgr/sgr_2004/index.htm

24. U.S. Department of Health and Human Services. *Women and Smoking: A Report of the Surgeon General.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2001. Available at http://www.cdc.gov/tobacco/sgr/sgr_forwomen/index.htm.

25. Agency for Health Care Policy and Research. *Treating Tobacco Use and Dependence: A Public Health Service Clinical Practice Guideline.* Rockville, MD: Agency for Health Care Policy and Research, 2000. Available at http://www.ahrq.gov/clinic/tobacco/.

26. CDC. Chapter 1. The role of quitlines in comprehensive tobacco control programs. In: *Telephone Quitlines: A Resources for Development, Implementation, and Evaluation.* Atlanta: U.S. Department of Health and Human Services, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on

Smoking and Health, 2004. Available at http://www.cdc.gov/tobacco/quitlines.htm.

27. Lichtenstein E, Glasgow RE, Lando HA, et al. Telephone counseling for smoking cessation: rationales and meta-analytic review of evidence. *Health Education Researc*h 1996;11(2):243–257.

28. Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, 2000.

29. Hopkins DP, Briss PA, Ricard CJ, et al. Reviews of evidence regarding interventions to reduce tobacco use and exposure to environmental tobacco smoke. *American Journal of Preventive Medicine* 2001;20(Suppl 2):16–66.

30. Stead LF, Lancaster T, Perera R. Telephone counselling for smoking cessation (Cochrane Review). In: *The Cochrane Library* 2004, Issue 1. Chichester, UK: John Wiley & Sons, Ltd, 2004.

Additional Resources

Healthy Eating

American Diabetes Association Medical Nutrition Therapy
http://care.diabetesjournals.org/cgi/content/full/28/suppl_1/s4#SEC6

NHLBI's Obesity Education Initiative
http://www.nhlbi.nih.gov/about/oei

CDC
How to Use Fruits and Vegetables to Help Manage your Weight
http://www.cdc.gov/nccdphp/dnpa/nutrition/weight.htm

CDC
Can eating fruits and vegetables help people to manage their weight?
Research to Practice Series, No. 1
http://www.cdc.gov/nccdphp/dnpa/nutrition/pdf/rtp_practitioner_10_07.pdf

National Cancer Institute, 5 A Day
http://www.5aday.gov/

Produce for Better Health Foundation, 5 A Day
http://www.5aday.org/

Dole Food Company, 5 A Day
http://www.dole5aday.com

Community Guide to Preventive Services—Nutrition
http://thecommunityguide.org/nutrition/default.htm

Task Force on Community Preventive Services—Healthy Diet Counseling
http://www.ahrq.gov/clinic/uspstf/uspsdiet.htm

American Dietetic Association
http://www.eatright.org

Diabetes Prevention Program lifestyle manuals and materials for the 16 intervention sessions
http://www.bsc.gwu.edu/dpp/manuals.htmlvdoc

Physical Activity

Surgeon General's Report on Physical Activity and Health
http://www.cdc.gov/nccdphp/sgr/contents.htm

CDC's Division of Nutrition and Physical Activity
http://www.cdc.gov/nccdphp/dnpa/physicalactivity.htm

The Community Guide to Preventive Services, Increasing Physical Activity
http://www.thecommunityguide.org.

Growing Stronger: Strength Training for Older Adults
http://www.cdc.gov/nccdphp/dnpa/physical/growing_stronger/index.htm

National Blueprint: Increasing Physical Activity Among Adults Age 50 and Older
http://www.cdc.gov/nccdphp/dnpa/press/archive/blueprint.htm

National Blueprint Office Awards Mini-Grants to Community Physical Activity Programs
http://www.agingblueprint.org/ViewArticle.cfm?id=76&class=2

Promoting Active Lifestyles Among Older Adults
http://www.cdc.gov/nccdphp/dnpa/physical/pdf/lifestyles.pdf

Physical Activity & Public Health (PAPH) Courses
http://prevention.sph.sc.edu/seapines/index.htm

Tobacco Use Cessation

Surgeon General Reports
http://www.cdc.gov/tobacco/sgr/index.htm

Guide to Preventive Services—Tobacco Use Prevention and Control
http://www.thecommunityguide.org/tobacco/

National Quitline, a toll-free number that routes callers to free cessation services that include information and phone counseling. Anyone in the United States can call.
1-800-QUIT-NOW

Online guide to quit smoking
http://www.smokefree.gov

CDC Tobacco Information and Prevention Source (TIPS)
http://www.cdc.gov/tobacco

CDC Cessation Resource Center
http://apps.nccd.cdc.gov/crc/

Center for Tobacco Cessation
http://www.ctcinfo.org

Raising Awareness about Women and Heart Disease

The Heart Truth Campaign for Women
http://www.nhlbi.nih.gov/health/hearttruth/index.htm

National Heart, Lung, and Blood Institute (NHLBI)
The Heart Truth Campaign—a National Awareness Campaign for Women about Heart Disease. Questions To Ask Your Doctor
http://www.nhlbi.nih.gov/health/hearttruth/lower/askdoctor.htm

Heart Attack Warning Signs for Women
http://www.nhlbi.nih.gov/actintime/haws/women.htm

American Heart Association
http://www.americanheart.org

CDC Office of Minority Health
http://www.cdc.gov/omh/

CDC Office of Women's Health
http://www.cdc.gov/od/spotlight/nwhw/default.htm

Other Topics

Steckler A, Linnan L, eds. *Process Evaluation for Public Health Intervention and Researchers.* San Francisco: Jossey-Bass, 2002.

American Heart Association Guide for Improving Cardiovascular Health at the Community Level: A Statement for Public Health Practitioners, Healthcare Providers, and Health Policy Makers From the American Heart Association Expert Panel on Population and Prevention Science
http://circ.ahajournals.org/cgi/reprint/107/4/645

Preventing Cancer, Cardiovascular Disease, and Diabetes: A Common Agenda for the American Cancer Society, the American Diabetes Association, and the American Heart Association
http://circ.ahajournals.org/cgi/reprint/109/25/3244

5

Evaluating Your Efforts and Demonstrating That WISEWOMAN Works

Chapter 5: Evaluating Your Efforts and Demonstrating That WISEWOMAN Works

In this chapter, you will learn about our evaluation philosophy and the frameworks we use to guide WISEWOMAN evaluation efforts. We also discuss the goals of the WISEWOMAN program, the types of data CDC needs to evaluate the WISEWOMAN program, and how our evaluation results are used. Finally, we discuss evaluating at the project level.

WISEWOMAN Evaluation

WISEWOMAN evaluation consists of two types of evaluation at the project and program levels: (1) process evaluation and (2) outcome evaluation. We believe that evaluation should be conducted not only to demonstrate impact and effectiveness, but also to improve programs and contribute to knowledge of what works. Evaluation should provide useful information to document the value of a program, guide program implementation and management, demonstrate accountability, and lead to greater learning opportunities. At the very least, it should provide a solid base for decision-making that ultimately leads to stronger and more effective programs.

Evaluation for the WISEWOMAN program is a systematic assessment that provides useful information to document the value of our program, guide program implementation and management, demonstrate accountability, and lead to greater learning opportunities.

Evaluation Frameworks

CDC's Framework for Program Evaluation in Public Health

In 1999, CDC developed a Framework for Program Evaluation in Public Health.[1] This framework focuses on the integration of evaluation and program management so that the results can help guide planning, improve programs, and ultimately lead to better public health outcomes. We support this vision and build upon CDC's evaluation framework as the foundation for WISEWOMAN evaluations.

The CDC evaluation framework consists of six steps that must be taken in any evaluation:

1. Engage stakeholders.
2. Describe the program.
3. Focus the evaluation design.
4. Gather credible evidence.
5. Justify conclusions.
6. Ensure use and share lessons learned.

This framework is particularly helpful in describing a major goal of all WISEWOMAN evaluations: to ensure that the results are used and lessons learned are shared with others. Below, we list each of the steps in this framework and discuss how each step applies to the overall CDC WISEWOMAN program.

1. **Engage stakeholders:** An evaluation begins with engaging the stakeholders (i.e., the people or organizations who have a vested interest in what will be learned in the evaluation and how the results will be used). It is important to understand stakeholders' perspectives so that the end result addresses the questions that they are interested in. Failure to take these perspectives into account can result in evaluation findings being criticized, rejected, or ignored. For example, stakeholders at the WISEWOMAN program level include all of the WISEWOMAN projects, Congress, and partners. However, at the project level, your stakeholders include screening providers, lifestyle interventionists, state legislators, community partners, and women participating in your project.

2. **Describe the program/activity:** A program description is the frame of reference for subsequent decisions made in the evaluation. Descriptions should detail the program's stage of development, its context and history, the need for services, its activities, the primary goals and objectives of the program, how it effects change, and expected effects. A logic model (often displayed as a flowchart, map, or table) should be used to describe the sequence of events that lead to change. It links the processes to the eventual effects. (See Appendix L.)

3. **Focus the evaluation design:** The evaluation must be focused to address the concerns of the stakeholders and to work within the context of the program. Focusing the evaluation design includes

describing the purpose of the evaluation, explaining who will use the findings, explaining how the findings will be used, and identifying which evaluation questions will be answered. Data collection should also be described, including what information sources will be used, how the data will be collected, and who will collect, analyze, and interpret the data and present results. The design (e.g., experimental, quasi-experimental, observational) should also be detailed.

4. **Gather credible evidence:** Evaluation findings must be credible for stakeholders to use them. The information must be linked to the evaluation questions, which were developed considering the stakeholders' perspectives. Consulting specialists in research or evaluation methodology might be necessary to reduce the potential for drawing inaccurate conclusions. Such specialists can provide suggestions about how to enhance the credibility of inferences from the data. The key is to accurately describe program effects when they exist and identify alternative explanations when they occur. The WISEWOMAN program has identified minimum data elements, cost data elements, and performance indicators to assist with program evaluation.

5. **Justify conclusions:** Conclusions are justified when they are linked to the evidence gathered. Alternative explanations for the results should be ruled out with evidence. Conclusions are judged against the stakeholders' standards or indicators of performance to see if they are justified. Stakeholders must agree that the conclusions are justified before they will use the results with confidence. To justify conclusions of data analysis for which a WISEWOMAN performance standard has not been identified, the interpretation of findings, judgment, and recommendations are identified using a team approach; at a minimum, CDC staff, an RTI contractor, and project staff are involved.

6. **Ensure use and share lessons learned:** Deliberate action is needed to ensure use and share lessons learned. The stakeholders responsible for the evaluation must ensure that the findings are used and disseminated to all other stakeholders. Effective strategies include using a user-friendly format to describe findings, requesting feedback from other stakeholders, following up with stakeholders, and disseminating a final report of findings. Findings from project-level data analysis are reviewed and discussed with key staff on a project-by-project basis. Findings from aggregate data analysis are shared with all WISEWOMAN projects at annual meetings and teleconferences. The WISEWOMAN Publications Subcommittee provides input on publications that are developed to share WISEWOMAN results with broader audiences.

Standards for Program Evaluation: The CDC framework also addresses the importance of following the standards for effective evaluations. The standards were developed by the Joint Committee on Standards for Education Evaluation[2] and are recognized as the guide to sound evaluation practice. The standards suggest that all evaluations should involve procedures that are useful, feasible, ethical, and accurate. WISEWOMAN requires all its evaluations to adhere to these standards. The standards are briefly described below.

1. **Utility standards:** Utility standards ensure that the information needs of the users of the evaluation findings are met. Seven utility standards address items such as identifying those who will be affected by the evaluation, the amount and type of the information collected, the values used in interpreting the findings, and the clarity and timeliness of evaluation reports.

2. **Feasibility standards:** Feasibility standards ensure that the evaluation is viable and pragmatic. The three feasibility standards emphasize using practical procedures, taking differing political interests into account, and ensuring the prudent use of resources.

3. **Propriety standards:** Propriety standards ensure that an evaluation is ethical. The eight propriety standards address items such as developing protocols and other agreements to guide the evaluation, protecting the welfare of human subjects, weighing and disclosing findings in a complete and balanced fashion, and addressing any conflicts of interest.

4. **Accuracy standards:** Accuracy standards ensure that the evaluation produces findings that are considered correct. Twelve accuracy standards address the importance of describing the program and its context, detailing the purpose and methods of the evaluation, employing systematic procedures to gather valid and reliable data, using appropriate qualitative and quantitative procedures when appropriate, and producing impartial reports containing conclusions that are justified.

Using the RE-AIM Framework to Focus the Evaluation Design

WISEWOMAN is not only concerned with demonstrating effectiveness, but also evaluating the broader public health impact of the program. The RE-AIM framework[3] is a systematic approach to planning and evaluation that is concerned with maximizing public health impact (see www.re-aim.org and Chapter 1 of this book for more details about

RE-AIM). It is an approach to evaluation that moves beyond effectiveness to include other dimensions that, when taken together, describe the broader public health impact of a program. The dimensions, as they apply in the context of WISEWOMAN, are described below:

Reach: The absolute number, proportion, and representativeness of individuals who participate in WISEWOMAN program activities such as recruitment, screening, and interventions.

Effectiveness: The impact of an intervention (or other program activities) on outcomes that are important to WISEWOMAN, including potential negative effects, quality of life, and economic outcomes.

Adoption: The absolute number, proportion, and representativeness of settings and service providers who are willing to initiate a WISEWOMAN program, intervention, or other program component.

Implementation: At the setting level, implementation refers to the service providers' (e.g., those who provide screening and LSI) fidelity to the various elements of the protocol. This includes consistency of delivery as intended and the time and cost of the service.

Maintenance: The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Maintenance in the RE-AIM framework also has referents at the individual level. At the individual level, maintenance has been defined as the long-term effects of a program on outcomes after 6 or more months following the most recent intervention contact.

RE-AIM helps focus the evaluation design because it defines the scope of WISEWOMAN evaluations. The RE-AIM dimensions are used to define our evaluation questions and data collection needs. Evaluation questions and the eventual data collection meant to answer those questions will be categorized to some extent into a specific RE-AIM dimension. However, it is important to remember that the dimensions are interconnected, which means an evaluation question might fall under multiple categories.

WISEWOMAN Program Goals

To start the evaluation process, we must first look at our program goals because they help us identify what is valued and what is important to the program. The WISEWOMAN program has long-term goals that describe what we hope to achieve in the next 5–10 years. We have organized these goals under each of the RE-AIM dimensions:

We use minimum data elements, cost data, and the performance indicators listed in Table 5.2 to help us determine if the goals are achieved.

Reach

R-1 To build a national WISEWOMAN program that provides every eligible NBCCEDP woman with an opportunity for WISEWOMAN services.

R-2 To establish a WISEWOMAN program that reaches NBCCEDP women with the highest cardiovascular disease (CVD) risk, including racial/ethnic minority women in numbers that represent the proportion seen in NBCCEDP.

R-3 To establish a WISEWOMAN program where at least 60%–75% of the women screened receive the culturally appropriate lifestyle intervention (LSI).

Effectiveness

E-1 To establish a WISEWOMAN program that improves lifestyle behaviors.

E-2 To establish a WISEWOMAN program that improves women's CVD risk scores.

E-3 To ensure that WISEWOMAN is a cost-effective program.

Adoption

A-1 To establish a WISEWOMAN program that is easy to adopt.

Implementation

I-1 To establish a WISEWOMAN program that can be delivered as intended.

Maintenance

M-1 To establish that the benefits of the WISEWOMAN program can be maintained over time at the individual level.

M-2 To establish that the activities of the WISEWOMAN program can be sustained over time at the organizational level.

Government Performance and Results Act

The data that you collect are very important to us because we, as a federal agency, must be accountable to Congress and other stakeholders. The Government Performance and Results Act (GPRA), established in 1993, requires that every major federal agency ask some very basic questions: What is our mission? What are our goals, and how will we achieve them? How can we measure our performance? How will we use that information to make improvements? We use your data to answer these important questions and remain accountable.

Collecting Data for Evaluation

Policy on Minimum Data Elements and Cost Data Reporting

Your project should collect and report minimum data elements and cost information in the format suggested by the program to its evaluation contractor (Research Triangle Institute) twice a year:

Report on April 15	Data collected from program inception through December 31 of the previous year
Report on October 15	Data collected from program inception through June 30 of the current year

Minimum Data Elements

Minimum data elements (MDEs) are a set of standardized data elements that we need to evaluate the WISEWOMAN program. To reduce the burden on your WISEWOMAN participants and to avoid duplication, we have taken some of the WISEWOMAN MDEs (such as demographic variables) directly from the NBCCEDP data collection systems. Other MDEs have been developed with input from WISEWOMAN projects specifically for the WISEWOMAN program.

Results of cardiovascular disease risk factor screening, health behavior questions, and intervention attendance, plus data used to monitor the care of women with alert values, are all part of the MDE submission. These data elements are used to determine the performance of each

WISEWOMAN project and the impact of the overall WISEWOMAN program.

The WISEWOMAN program contracts with RTI to use the MDE and cost data collected from the projects to evaluate the impact of the program. RTI provides technical assistance, reports, and other sources of feedback to projects based on the results of the data analysis. Your project must submit to RTI minimum data elements on screening and the lifestyle intervention, as well as cost data.

For a complete list of screening and intervention MDEs, please see the WISEWOMAN Data User's Manual. For more information on how to report cost data, please see the WISEWOMAN Cost Primer. Both documents can be downloaded from http://wisewoman.rti.org.

Minimum Data Elements on Screening

You are required to report the following MDEs for each participant:

- Blood pressure (two readings).
- Total cholesterol and high-density lipoprotein cholesterol.
- Height and weight.
- Medical history (e.g., Have you ever been told by a doctor, nurse or other health professional that your blood cholesterol is high?).
- Medication use (e.g., Are you currently taking medications for high cholesterol?).
- Health behaviors related to diet, physical activity, and smoking.

If your project also screens women for diabetes (and we highly recommend that you do), the results of blood glucose tests should also be reported.

MDEs on screening are to be collected at the baseline, evaluation (first annual), and annual office visits. You must report these MDEs semi-annually to RTI. When women are screened and found to have alert levels, you must document their referral and receipt of care and treatment as a minimum data element.

When you rescreen participants 10–14 months after the initial screening visit (conducting the same screening tests as at baseline and using the same health behavior questions asked during the initial visit), you must report these results as MDEs. Results from subsequent screening visits are also reported.

Minimum Data Elements on the Lifestyle Intervention

We collect MDEs to help determine if WISEWOMAN interventions have achieved the desired effects. Answers to health behavior questions are to be collected from women during the initial screening visit, before they attend the lifestyle intervention, and again 1 year (10–14 months) later at the evaluation (first annual) screening visit to determine if a change in behavior has occurred. Furthermore, the project must track each woman's participation in the lifestyle intervention.

Presently, the nutrition and physical activity behavior data elements vary across projects. However, discussions are under way with representatives from all funded projects (MDE Subcommittee members) to establish standardized nutrition and physical activity questions. The tobacco questions are already standardized.

Cost Data

The WISEWOMAN program, like all other federal government programs, is held accountable for the fiscal management of its resources. To determine cost effectiveness, all WISEWOMAN costs will be allocated to one of four WISEWOMAN-related activities. You must submit these cost data to RTI at the same time as your submit your MDEs.

Recruitment and tracking: Include costs associated with reaching women for the purpose of enrolling them in the program and maintaining contact with them throughout the period of funding to help ensure completion of LSI sessions and annual screening visit.

Screening: Include costs associated with collecting medical information about the participants. These activities include taking blood samples for glucose and cholesterol tests, measuring blood pressure, providing support services, and providing a professional assessment of the individual's health profile.

Intervention: Include costs associated with providing LSI-related activities. Counseling sessions, cooking classes, physical activity classes, and incentives are examples of activities or items captured in this category.

Program oversight and administrative: Include costs associated with activities required to administer the program. This category includes all WISEWOMAN costs not captured in the categories above.

Additionally, costs will be subdivided at the site level into labor, materials and supplies, and contracted costs. RTI has developed a primer that

provides much greater detail on collecting and reporting your cost data. Furthermore, RTI staff and your project officer will work with you to develop a method for capturing this information.

WISEWOMAN Performance Indicators

The WISEWOMAN program has developed performance indicators that allow projects to conduct continuous progress monitoring using a CDC standard. CDC, in many cases, based the standards on achievements made in the first phase of the program by the Massachusetts and North Carolina WISEWOMAN demonstration projects.[4] We will continue to work with WISEWOMAN projects to determine future performance indicators and standards as the WISEWOMAN program develops.

Table 5.2. WISEWOMAN Performance Indicators

Performance Indicator	CDC Standard
Number of women to be screened each year for chronic disease risk factors and to receive risk-reduction counseling based on the screening results. The minimum number of women that a project is to screen is determined by the type of project (standard or enhanced) and the funding level (level one or level two, per Appendix B in Program Announcement 03022). Standard projects that receive level one funding are to screen a minimum of 500 women each year. Standard projects that receive level two funding are to screen a minimum of 2,500 women each year.	At least 2,500 (Standard, Level 2) At least 500 (Standard, Level 1)
The minimum number of women screened for enhanced (intervention research) projects is individualized and based on power calculations.	**Power calculations are used for enhanced projects.**
Percentage of new WISEWOMAN participants screened who return for the evaluation (first annual) screening visit within 10–14 months from baseline screening. This is required for purposes of program evaluation.	≥ 75%
Percentage of new women screened who attend at least one standardized lifestyle intervention session. For enhanced projects, this relates only to women in the intervention group, not the control group.	≥ 75%
Percentage of new women screened who have completed standardized lifestyle intervention sessions. For enhanced projects, this relates only to women in the intervention group, not the control group.	≥ 60%
Failure to complete diagnostic/medical follow-up for women who have an alert screening value.	≤ 5%
Demonstrate that participants adopt a healthier lifestyle during the year following baseline screening.	TBD*
Demonstrate a reduction in expected cardiovascular disease events and deaths, per 1,000 women, in the next 10 years.	TBD

* TBD = to be determined.

Your Evaluation Plan

You must submit an evaluation plan to CDC each year with your interim progress report. Even though enhanced WISEWOMAN projects establish an evaluation plan at the beginning of the project period that encompasses the entire project period (typically this is a 5-year plan), minor changes may have occurred, and it is appropriate to resubmit the plan with the interim progress report. You will want to work with your evaluation team to identify milestones or significant accomplishments that need to occur within the next budget period, and performance or outcome measures for these objectives should be included in your evaluation plan. We encourage you to use the evaluation frameworks mentioned at the beginning of this chapter. Although the performance indicators and RE-AIM framework include process and outcome measures that you can use to evaluate progress and impact, projects interested in improving their program will want to include additional evaluation activities.

Beyond the MDEs: Evaluating at the Project Level

When you evaluate your lifestyle intervention or screening services, **look beyond the required MDEs** and consider questions you can ask that will help you identify which activities are working well and which activities need improvement.

Each year, your staff should identify activities that will be monitored to determine if these activities should continue, be modified, or be discontinued. For example, you will want to evaluate new strategies, such as those used to recruit women to your project, to determine if these strategies are a good use of resources.

In addition, you may want to consider analyzing client data to ensure that women receive timely and appropriate screening, diagnostic, and treatment services. Your project might also want to collect data to evaluate areas that may need improvement. You have the flexibility to develop your own activities for your quality improvement or evaluation plan. If you need help getting started, contact your project officer or consider some of the ideas below:

- Compare WISEWOMAN screening numbers with BCCEDP screening numbers at the same site to determine if efforts to recruit women within the BCCEDP are effective.
- Audit training records to ensure that key personnel have received training on both program and national guidelines.

Emphasis Is on the First 12 Months of Participation in WISEWOMAN

Focusing on the first 12 months of a woman's participation in the project is critical to the success of the WISEWOMAN program. Women should complete the initial screening visit, the LSI, and the evaluation (first annual) screening visit. Data from each of these visits are captured during the first year and are analyzed to determine the impact of the program.

- Survey health care practitioners to determine how they ensure that women who need pharmacological treatment receive low-cost or free medication for as long as they need it.
- Survey participants to determine if they are able to obtain free or low-cost medication.
- Survey participants to determine if they understand the results of their screening examinations.
- Analyze screening results at the clinic level and create population-based reports for practitioners who see several WISEWOMAN participants. This information might help providers determine if their treatment protocols are effective.
- Survey participants to determine if they received information from their provider to help them self-manage their health.

In their book, *Process Evaluation for Public Health Intervention and Researchers,*[5] Steckler and Linnan write that at the very least, process evaluators should collect data to determine the following factors:

- **Context,** including documentation of recruitment efforts: the environment that may influence how the intervention is implemented.
- **Reach:** The proportion of the intended target audience that participates in the intervention. Reach is often measured by attendance. (For example, you could look at the percentage of eligible BCCEDP women who participate in WISEWOMAN.)
- **Dose delivered:** The number of sessions that the intervention provider delivers. Dose received is the extent to which participants engaged in the session.
- **Fidelity:** The extent to which the intervention was delivered as planned. Fidelity represents the quality and integrity of the intervention as conceived by the developers.

Your project should work with experienced evaluators to plan, implement, and assess evaluation efforts that identify which parts of the screening lifestyle intervention services are working well and which parts should be modified or dropped. Once your project identifies

which evaluation questions will provide this information, you can develop methods to fill the gap between CDC's required minimum data elements and the data needed to answer your questions. For example, your project may want to determine if the intervention activities were carried out equally at all sites, or you may want to assess the quality and accuracy of the intervention delivered to participants. You will then need to develop a data collection instrument or identify other methods to collect this information.

Your evaluations might include assessments to determine increases in partnership efforts as a result of your project, improvements in medical care, system-level changes to increase the use of national clinical care or prevention guidelines, improvements in reminder systems to increase participation, the usefulness of community health workers in the project, increases in neighborhood assets, increases in provider knowledge, improvements in participants' self-efficacy, and so forth. This information may be collected through various methods such as surveys, success stories, in-depth interviews, observation, audits, and focus groups.

You can use the WISEWOMAN work, evaluation, and training plan template (see Appendix H) to fulfill the program's requirement for submitting an annual evaluation plan.

References

1. CDC. Framework for Program Evaluation in Public Health. *MMWR* 1999;48(No. RR-11). Available at http://www.cdc.gov/eval/framework.htm.

2. The Joint Committee on Standards for Educational Evaluation. *The Program Evaluation Standards: How to Assess Evaluations of Educational Programs.* 2nd edition. Thousand Oaks, CA: Sage; 1994.

3. Workgroup to Evaluate and Enhance the Reach and Dissemination of Health Promotion Interventions. RE-AIM Web site. Available at www.re-aim.org.

4. Center for Health Promotion and Disease Prevention, The University of North Carolina (UNC) at Chapel Hill. *Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program.* Chapel Hill, North Carolina: UNC, 2001. Available at www.hpdp.unc.edu/wisewoman/.

5. Steckler A, Linnan L, eds. *Process Evaluation for Public Health Intervention and Researchers.* San Francisco: Jossey-Bass; 2002.

Appendixes

Policy Development Framework for the WISEWOMAN Program

Appendix A
Policy Development Framework for the WISEWOMAN Program

Steps in Policy Development

Step 1	Summarize existing policies.
Step 2	Routinely solicit input for new policy areas.
Step 3	Select a policy topic through a systematic process.
Step 4	Identify policy development panelists.
Step 5	Define the purpose and scope of the proposed policy.
Step 6	Collect and synthesize information, options, and scientific evidence, as needed.
Step 7	Devise a method to deliberate and to make judgments and recommendations.
Step 8	Write, edit, and format the policy for review.
Step 9	Provide for peer review and legal review.
Step 10	Prepare final policy for dissemination.
Step 11	Disseminate policy in the policy and procedure manual.
Step 12	Maintain a system for periodic review and updates, as needed.

WISEWOMAN's Definition of Policy

A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions. Source: Webster's Dictionary.

Step 1	**Summarize existing policies.** Before the need for new policies can be determined, existing policies must be identified and reviewed. Users of the policies will have easy access to existing policies, such as by electronic access to a policy and guidance manual. CDC will determine whether any existing policies are not being used or followed.
Step 2	**Routinely solicit input for new policy areas.** The need for new policies is routinely assessed through a systematic process, such as annual surveys to program directors/ coordinators, focus groups of program directors/coordinators, or other means. New policy areas will emerge throughout the life of the program for various reasons: • New technologies become available, and projects need to know CDC's policy on use of a new technology, particularly under the terms of the cooperative agreement. • Policies affecting CDC may have a ripple-down effect, requiring some new action by projects to meet a new requirement imposed on CDC. • Controversies (a clash of opposing views) emerge among projects that can benefit from a systematic process to create a written policy.

	In addition to routine assessment of policy needs, CDC and projects can both propose policy area needs at any time during the year. For example, a project may submit a policy suggestion to an identified CDC staff person via e-mail. The process used to determine policy needs will be documented. See Step 10.
Step 3	**Select a policy topic through a systematic process.** Not all potential policy areas will require formal policies. Criteria for policy area selection include: • Change in legislative requirements. • National guideline updates. • Project/practitioner need or request for policy. • Variation in existing practice (if all projects are already identical in their actions, a policy may not be needed). • Potential impact on morbidity, mortality, and quality of life. • The cost, time, and resources for developing a policy are weighed against the anticipated benefits of a new policy. • Areas of controversy, including adoption of new technologies, may present special cases for which federal-level policy is useful. All policies will support the mission of CDC, the Division for Heart Disease and Stroke Prevention (DHDSP), and WISEWOMAN. The process used for policy selection will be documented. See Step 10.
Step 4	**Identify policy development panelists.** Methodology will allow for fair and balanced project representation on the policy development panel. Objectivity and expertise are

	desired attributes of panel members. The panel composition will seek multidisciplinary and multicultural representation. Some policies may require consultation with CDC's Office of the General Counsel. Core members of the policy development panel include: • CDC WISEWOMAN Team (all CDC project officers and team leader). • DHDSP Office of the Director representative. • All project coordinators and directors and other project representatives, as appropriate to the topic. Depending on the policy topic, council from experts such as the consultant group and/or within CDC may be solicited. For example, programs implementing policies related to nutrition or physical activity may request guidance from the Division of Nutrition and Physical Activity (DNPA), and those with policies related to diabetes may request guidance from the Division of Diabetes Translation (DDT). The composition of the policy development panel will be documented. See Step 10.
Step 5	**Define the purpose and scope of the proposed policy.** The intended audience for the policy will be made clear. Language in the policy will distinguish between **promising practices**, which may be recommended, and **program requirements**. The purpose and scope of the policy will be documented. See Step 10.

Step 6	**Collect and synthesize information, options, and scientific evidence, as needed.** In technical areas, scientific or medical evidence may be needed for consideration by the policy development panel. Criteria for assessment of evidence will be established on a case-by-case basis. For example, in the *Guide to Community Preventive Services*, the Task Force on Community Preventive Services provides clear and systematic guidelines to determine what literature is included in literature reviews and how this evidence is weighted in developing recommendations. As noted in Step 4, subject matter experts may also be consulted. In nontechnical areas, relevant information will be collected and synthesized. Viable options should be explored. The process used for collecting and synthesizing information will be documented. See Step 10.
Step 7	**Devise method to deliberate and to make judgments and recommendations.** The preferred method for policy discussions is to convene the policy development panel in conjunction with the scheduled annual WISEWOMAN project consultant meeting, as needed. Group interaction methods will be used to facilitate a productive meeting. CDC will consider advisement from the panel. If time does not allow for this, a teleconference will be arranged. The process used to facilitate group deliberations and decision-making will be documented. See Step 10. CDC makes all final policy determinations.

Step 8	**Write, edit, and format the policy for review.** CDC staff will write the policy and use language matched to the intended audience, subject matter, intention of the policy, and the dissemination vehicle.
Step 9	**Provide for peer review and legal review.** If appropriate, the proposed policy may undergo legal review by CDC's Office of General Counsel. Proposed policies will be reviewed by the following stakeholders: • All project coordinators and directors. • CDC WISEWOMAN Team. • DHDSP Office of the Director representative. • National Breast and Cervical Cancer Early Detection Program. • Internal medical advisors in CDC's divisions (DHDSP, DNPA, DDT, and Division of Cancer Prevention and Control), as needed. • Legislative advisors, as needed. A 45-day comment period will be allowed. Comments received from reviewers will be considered and the policy revised, as appropriate. The process of soliciting the reviews and responses will be documented. See Step 10.

Step 10	**Prepare final policy for dissemination.** The background information for the policy may state the following: • To whom the policy applies. • The problem it addresses (or the reason the policy was developed). • A clear and explicit description of what is being recommended. • Evidence to support the recommended course of action (e.g., scientific evidence of effectiveness of a new technology). • When the policy goes into effect (and when it expires). • What degree of implementation is expected from programs. • To the extent known, the expected costs and benefits of following the course of action recommended. • The performance measures associated with this policy. • What policy development methods were used. • Who participated in the creation of the policy. • Contact information. Pertinent documentation noted for Steps 2–9 will be included in the background section for each policy.

Step 11	**Disseminate policy in the policy and procedure manual.** The WISEWOMAN Guidance Document will be updated to reflect new policies. Each new policy will be disseminated to WISEWOMAN coordinators, program directors, and program staff. In addition, policies relevant to other programs, such as the National Breast and Cervical Cancer Early Detection Program, will be disseminated to appropriate staff. A hard copy of the policy will be sent to each project coordinator/ director, and an electronic version will be made.
Step 12	**Maintain a system for periodic review and updates, as needed.** The WISEWOMAN Guidance Document will be reviewed annually by the CDC WISEWOMAN Team.

Procedures for Fast-Track Policy Development

There may be times when a new policy must be developed, reviewed, and disseminated expediently in response to a time-sensitive request. To accommodate such time constraints, CDC will develop the policy through a fast-track process.

To develop the policy through the fast-track process, the following steps will be completed or omitted, as indicated below.

Step	Complete	Omit
1. Summarize existing policies.	Done	
2. Routinely solicit input for new policy areas.		X
3. Select a policy topic through a systematic process.		X
4. Identify policy development panelists.		X
5. Define the purpose and scope of the proposed policy.	X	
6. Collect and synthesize information, options, and scientific evidence, as needed.	X	
7. Devise a method to deliberate and to make judgments and recommendations.	Expedite	
8. Write, edit, and format the policy for review.	X	
9. Provide for peer review and legal review.	Expedite	
10. Prepare final policy for dissemination.	X	
11. Disseminate policy in the policy and procedure manual.	X	

Appendix B

Definitions of Key WISEWOMAN Terms

Appendix B
Definitions of Key WISEWOMAN Terms

Abnormal Values
Abnormal screening values for the WISEWOMAN program are the same as those listed in national clinical care guidelines. If a participant has an abnormal screening value, she is referred to a health care provider in accordance with the national clinical care guidelines. Abnormal values include:

- Blood pressure: systolic ≥140 mm Hg or diastolic ≥90 mm Hg.
- Nonfasting cholesterol: total cholesterol ≥200 mg/dL or high-density-lipoprotein cholesterol (HDL-C) <40 mg/dL. However, if the woman has normal total cholesterol and HDL-C, yet has multiple (≥2) risk factors, lipoprotein measurement is recommended as a guide to clinical management.
- Fasting cholesterol: depends on low-density lipoprotein cholesterol (LDL-C) measurement and a number of risk factors. For example, both an LDL-C ≥130 mg/dL with <2 risk factors and an LDL-C ≥100 mg/dL with ≥2 risk factors are considered abnormal.
- Nonfasting blood glucose (casual): ≥200 mg/dL with symptoms.
- Fasting blood glucose: ≥126 mg/dL.

Alert Values
The purpose for identifying alert screening values is twofold:

1) Blood pressure and blood glucose alert values are measures that are considered dangerously high by the WISEWOMAN program and indicate that a woman should receive immediate medical attention. Although the alert value for cholesterol may not be life threatening, expert consultants have suggested that a person with a level greater than 400 mg/dL also receive timely medical attention.

2) Although the program requires that a referral system be in place to ensure that women with an abnormal screening value receive appropriate follow-up medical care, resources do not allow projects to track and follow women to determine if this occurs, except in the case of women who have alert screening values. The project is required to collect data that establish that women with alert screening values receive timely and appropriate care. This information can be used by the project to determine if the referral systems used by their screening providers are working effectively. This information is used by the

program to assure Congress and other interested stakeholders that systems are in place to ensure that women receive timely and appropriate medical care. Alert values are:

- Blood pressure >180/110 mm Hg.
- Blood cholesterol >400 mg/dL.
- Fasting blood glucose >375 mg/dL.

Allowable Screening Tests

Screenings are defined as preliminary tests used to detect signs of a disorder that may require further investigation. Screening services are made available through health care facilities or other community-based organizations that can meet Clinical Laboratory Improvement Amendments (CLIA) standards and that agree to adhere to national clinical care guidelines. WISEWOMAN funds are allowed to reimburse for screening tests or procedures that provide the following measures:

- Resting pulse.
- Blood pressure.
- Serum total cholesterol.
- HDL-C (nonfasting).
- Height and weight.
- Panels that include assessment of blood glucose.
- Urine analysis.
- Paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems.

Allowable Diagnostic Tests

Diagnostic tests are defined as tests and procedures used to identify a disease state or to aid in a diagnosis. Diagnostic services are made available by a physician but also may be performed by nurses or other health professionals who agree to adhere to national clinical care guidelines. WISEWOMAN funds may be allowed to pay for these diagnostic tests only:

- Fasting lipoprotein analysis.
- Fasting blood glucose.
- Oral glucose tolerance test (OGTT).

Annual Screening
WISEWOMAN funds may be used to reimburse for annual screenings that occur beyond the initial and evaluation (first annual) screening visit for women who are still eligible to participate in the program. Each WISEWOMAN participant will have the same screening tests administered and answer the same behavioral or health risk appraisal questions that were asked at her initial screening. These measurements are collected and reported every year that she participates in the program.

Atherogenic Diet
An atherogenic diet is one that is high in saturated fatty acids and dietary cholesterol. The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III) considers an atherogenic diet to be an underlying risk factor for coronary heart disease.

Capacity Building
Before a WISEWOMAN project can influence individuals and organizations to make the changes needed for success, the project might require resources, knowledge, and skills above and beyond those it already has. Building capacity for the WISEWOMAN projects includes hiring appropriate staff and developing staff and providers through training efforts that increase adherence to national clinical care guidelines and intervention protocols. Further, an increase in knowledge and skills regarding the impact of cardiovascular disease risk factors, such as poor diet, inactivity, and tobacco use, are also needed to build capacity for the WISEWOMAN project.

Cardiovascular Disease
Cardiovascular disease (CVD) is a term used to include high blood pressure, coronary heart disease, and stroke. Some organizations use this term to include diseases of the heart and/or the circulatory system.

Case Management
WISEWOMAN funds may only be used to reimburse for case management activities for women with alert screening values. Case management is a program component that involves establishing, brokering, and sustaining a system of available clinical (screening, diagnostic, and treatment) and support services for all enrolled women who would ultimately be assessed to need case management services. Case management is considered the most intensive intervention in the continuum of care, and it is one of many strategies to improve adherence to national clinical guideline recommendations.

Clinical Follow-up
Clinical or medical follow-up is defined as all medical services (including medical care and support services aimed at improving adherence to medical care and treatment for the identified risk factors) provided to address the results of baseline screening. These services are delivered to the woman before her annual rescreening visit. Examples include simplifying medication regimens, reminding patients of upcoming medical appointments, and arranging for transportation to medical appointments.

Clinical Tracking
Clinical tracking is the recording and analysis of client data to ensure that a woman enrolled in the project receives timely and appropriate rescreening, diagnosis, and treatment services. Clinical tracking data are required for women who have alert screening values.

Community Health Worker
A community health worker (CHW) is an indigenous member of a specific population who delivers interventions (provides health promotion and health education services, conducts outreach, advocates for patients and clients, provides social support and community advocacy) in a manner consistent with local cultural beliefs, practices, and social norms. CHWs have been shown to be effective in promoting primary and secondary prevention messages and services and in increasing access to health care. Their work helps to fill in the gaps in the current health care system.

Coronary Heart Disease
Coronary heart disease (CHD) is caused by atherosclerosis, the narrowing of the coronary arteries due to fatty build-ups of plaque. CHD is likely to produce angina pectoris (chest pain), heart attack, or both. Risk factors for CHD include high blood pressure, high blood cholesterol, smoking, obesity, and physical inactivity—all of which can be controlled.

Demonstration Projects
Congress has authorized the Centers for Disease Control and Prevention to fund WISEWOMAN projects to demonstrate the feasibility and effectiveness of providing preventive health services (such as CVD screening and behavioral or lifestyle interventions) for women enrolled in National Breast and Cervical Cancer Early Detection Program (NBCCEDP)-sponsored programs.

Eligibility Criteria
All women aged 40 and older who are enrolled and remain eligible to participate in the state, territory, or tribal organization's BCCEDP are eligible to participate in WISEWOMAN. A WISEWOMAN participant is a woman who meets the eligibility criteria and has completed all of the following:

1. Signed the consent form.
2. Answered health behavior questions (e.g., on a health risk appraisal form, lifestyle questionnaire, or enrollment form).
3. Been screened for at least one CVD risk factor.

Enhanced WISEWOMAN Project
The enhanced WISEWOMAN project is charged with conducting intervention research to test the effectiveness and cost-effectiveness of a behavioral or lifestyle intervention that is grounded in the social and cultural context of the target population and is aimed at preventing CVD. In addition, the enhanced project is charged with translating and transferring successful intervention and program strategies to other programs that serve financially disadvantaged women. Enhanced projects are strongly encouraged to work closely with a Prevention Research Center or other university partner.

Evidence-Based Intervention
An evidence-based intervention is one that has been evaluated and has demonstrated success in reducing cholesterol, blood pressure, and other indicators and has resulted in positive lifestyle outcomes. The *Guide to Community Preventive Services*, for example, provides evidence-based recommendations for interventions to increase physical activity.

Inreach
Recruitment strategies directed at women enrolled in the BCCEDP are called inreach strategies. These activities include contacting women enrolled in the BCCEDP through mail or telephone calls to encourage them to participate in WISEWOMAN services and/or working with the health care providers to promote WISEWOMAN services.

Intervention Follow-up or Management
Intervention follow-up encompasses all services provided outside the formal intervention session/program for the purpose of promoting attendance at intervention sessions and adherence to lifestyle interventions. Examples of these services include phone calls to offer support and encouragement and arrangements for transportation to intervention sessions.

Integrated Program
WISEWOMAN is an integrated program in that its services—including screening, risk reduction counseling, referral, lifestyle modification interventions, and a comprehensive evaluation—are integrated with existing services and evaluation efforts to provide preventive services to the intended population.

Lifestyle Intervention Process Measures
Intervention process measures allow for monitoring the number and types of intervention sessions a woman has received so that the dosage level or exposure can be determined. Process measures are also used to determine if the lifestyle intervention is implemented as intended.

Lifestyle Intervention Research
In enhanced projects, which are research programs, interventions are rigorously tested to determine which are most feasible and effective for changing diet, physical activity, and/or smoking behaviors within the WISEWOMAN target audience.

Lifestyle Intervention Tracking
Lifestyle intervention tracking is the recording and analysis of client data to ensure that a woman enrolled in the program receives the complete intervention.

Lifestyle Intervention Counseling
All WISEWOMAN participants are provided standardized lifestyle intervention counseling (counseling that uses the same methodology and educational materials across all sites). Nutritionists, health educators, or other qualified health care professionals (including trained community health workers) provide nutrition and physical activity counseling that supports national health promotion and disease prevention recommendations. The counseling can occur in an individual and/or group setting for the purpose of helping the participant identify her individual goals and to provide skills and knowledge needed to help her achieve and sustain heart-healthy behaviors. The participant may also receive counseling on topics such as smoking cessation, stress management, or osteoporosis prevention.

Lifestyle Intervention Counseling Sessions
Lifestyle intervention counseling sessions are the encounters or appointments held between the interventionist and participant to transfer the knowledge and skills necessary for behavior change. At the state/tribal level, WISEWOMAN projects determine the number of core or essential standardized lifestyle intervention counseling sessions needed for individual and program success. Success is based on meeting behavioral goals and objectives.

Medical Nutrition Therapy
The Medicare MNT benefit regulations define medical nutrition therapy (MNT) services as nutritional diagnostic, therapy, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing disease. WISEWOMAN funds may not be used to reimburse for medical nutrition therapy.

Minimum Data Elements
Minimum data elements (MDEs) are a set of standardized data elements developed and collected to ensure that consistent and complete information on screening location, patient demographic characteristics, screening results, diagnostic procedures, intervention tracking and follow-up, and diet, physical activity, and tobacco assessments are collected on women enrolled in the WISEWOMAN project. These are the data items that are minimally necessary for WISEWOMAN-sponsored projects and the CDC to monitor outcomes. The electronic MDE files are submitted semiannually to CDC or a designated contractor. Projects are encouraged to collect additional data for project management and evaluation purposes.

Monitoring
Monitoring is a quality assurance activity to assess the quality and level of adherence to the project's screening and intervention protocols. Strategies include site visits, audits, and other ongoing evaluation activities.

National Breast and Cervical Cancer Early Detection Program
The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is a program that focuses on service delivery and early detection of cancer. In 1995, Congress created WISEWOMAN as a supplemental preventive service program for clients enrolled in the NBCCEDP-funded programs. Through the NBCCEDP infrastructure in 15 project locations, WISEWOMAN services are provided. When the acronym BCCEDP is used, we are referring to the state or tribal organization's CDC-funded Breast and Cervical Cancer Early Detection Program.

Outreach
Outreach activities are strategies used to recruit eligible women previously not known by WISEWOMAN or BCCEDP staff. (By contrast, inreach activities are strategies used to recruit eligible women who are already known to the health care facility.)

Performance Indicators
WISEWOMAN has identified performance indicators to assist in monitoring and measuring a project's progress toward achieving program goals. Performance indicators help to identify a project's strengths and its opportunities for further improvement.

Project Period
WISEWOMAN projects are funded for a 3- to 5-year period, as noted in the program announcement's request for application.

Protocol
Protocols are written plans specifying the procedures to be followed by project staff or contractors. Protocols are developed to ensure that appropriate care is given to all WISEWOMAN participants.

Public Health Advisory Team
Projects are to work with experts selected to form an interdisciplinary team to provide advice on the direction of the project as well as specific project issues. These experts may include physicians, public health practitioners, nutritionists, interventionists, evaluation staff, participants, and others.

Referral
Referral is a process whereby a participant is introduced to additional health resources in the community, as in helping a woman find an appropriate provider for further diagnosis after receiving notice that her CVD screening values were abnormal. In addition, a referral may be used to provide a WISEWOMAN participant with a link to the intervention counseling she needs to improve her risk factor status.

Risk Reduction Counseling
Risk reduction counseling provides the participant with an interpretation of the results of screening tests and health risk assessment questions. WISEWOMAN strongly recommends that the risk reduction counseling be provided both in writing and orally.

Standard WISEWOMAN Project
The standard WISEWOMAN project is charged with evaluating the effectiveness (including cost-effectiveness) of operational approaches used to conduct WISEWOMAN activities such as outreach; screening to check blood pressure and cholesterol and to assess behaviors related to smoking, diet, and physical activity; referral; lifestyle intervention; tracking and follow-up; evaluation; professional and public education; and community engagement.

Therapeutic Lifestyle Changes
The National Cholesterol Education Program's document, *The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (ATP III), recommends the use of dietary therapeutic lifestyle changes (TLCs) to reduce cholesterol in the bloodstream through reduced fat and increased fiber intakes. According to the guidelines, a health care provider should initiate TLCs if a woman's LDL-C is above goal.

- Diet-related recommendations:
  - Saturated fat <7% of calories, cholesterol <200 mg/day.
  - Consideration for increased viscous (soluble) fiber (10–25 g/day) and plan stanols/sterols (2g/day) as therapeutic options to enhance LDL-C lowering.
- Weight management.
- Increased physical activity.

WISEWOMAN Consultant Group
CDC assembled the WISEWOMAN Consultant Group to advise CDC and its partners on issues relevant to the operation, evaluation, and sustainability of WISEWOMAN. The group is composed of eight nationally known experts who collectively bring extensive knowledge and experience in cardiovascular disease, women's health, public health practice and preventive medicine, access to care, health behavior and lifestyle interventions, and program evaluation.

WISEWOMAN Program
WISEWOMAN is an acronym that stands for **W**ell **I**ntegrated **S**creening and **E**valuation for **Wom**en **A**cross the **N**ation. The program comprises 15 WISEWOMAN projects, CDC staff, contractors, and other partners.

Appendix C

CPT Codes

Appendix C
CPT Codes

Allowable Primary Prevention Services with Corresponding CPT Codes[1]

The following list of Current Procedural Terminology (CPT) codes reflects those most commonly used by our currently funded WISEWOMAN projects. This list can be used to help new projects identify procedures that are approved for reimbursement or help established projects confirm that the procedures and services for which they plan to reimburse are allowed by the program. If your project would like to use a CPT code that is not included on this list, please discuss this with your project officer. Your project will be asked to annually submit its list of CPT codes and reimbursement rates for approval along with your continuation application and budget.

CPT Code	Cholesterol and Lipid Tests
80061	Lipid panel
80061QW	Lipid panel (CLIA-waived[2])
82465	Cholesterol, total
82465QW	Cholesterol, total (CLIA-waived)
83718	HDL cholesterol
83718QW	HDL cholesterol (CLIA-waived)
	Glucose Tests
82947	Glucose; quantitative
82947QW	Glucose; quantitative (CLIA-waived)
82948	Glucose; blood, reagent
82951	Glucose tolerance test, three specimens
82951QW	Glucose tolerance test, three specimens (CLIA-waived)
83036	Hemoglobin, glycated (HbA1c) *used in lieu of other glucose testing for those with previous diagnosis of diabetes*
83036QW	Hemoglobin, glycated (HbA1c) (CLIA-waived) *used in lieu of other glucose testing for those with previous diagnosis of diabetes*
	Panels That Include Glucose
80048	Basic metabolic profile
80053	Comprehensive metabolic panel

	Other Screening Activities
36415	Routine venipuncture
	Office Visits **(same as those allowed by the National Breast and Cervical Cancer Early Detection Program)**
99201	Office visit for new patient—problem focus—10 minutes face-to-face
99202	Office visit for new patient—expanded problem focus—20 minutes face-to-face
99203	Office visit for new patient—low complexity—30 minutes face-to-face
99211	Office visit for established patient—minimal problem—5 minutes face-to-face
99212	Office visit for established patient—problem focus—10 minutes face-to-face
99213	Office visit for established patient—expanded problem focus—15 minutes face-to-face
99241	Consultation visit—problem focus—15 minutes face-to-face
99242	Consultation visit—expanded focus—30 minutes face-to-face
99243	Consultation visit—detailed focus—40 minutes face-to-face
99385	Initial preventive medicine evaluation—30-39 years
99386	Initial preventive medicine evaluation—40-64 years
99387	Initial preventive medicine evaluation—≥65 years*
99395	Periodic preventive medicine evaluation—30-39 years
99396	Periodic preventive medicine evaluation—40-64 years
99397	Periodic preventive medicine evaluation—≥65 years*

* Reimbursable for Medicare Part B unenrolled women only.

Note: WISEWOMAN funds cannot be used to reimburse for the treatment of conditions such as high blood pressure, high cholesterol, high glucose, or obesity. Treatment includes medication, medical nutrition therapy, and other highly specialized counseling, such as diabetes-education programs.

Lifestyle Intervention Counseling	
Lifestyle intervention counseling to address healthy eating, physical activity and/or tobacco use is delivered and reimbursed through a variety of ways by our WISEWOMAN projects. Projects that use CPT codes for reimbursement of lifestyle intervention counseling may use the following codes, as appropriate. Maintenance activities are not included in this section.[3]	
99401	Individual, face-to-face or on the telephone, 15 minutes
99402	Individual, face-to-face or on the telephone, 30 minutes
99403	Individual, face-to-face or on the telephone, 45 minutes
99404	Individual, face-to-face or on the telephone, 60 minutes
99411	Face-to-face in group setting, 30 minutes
99412	Face-to-face in group setting, 60 minutes

[1] Level I of the Healthcare Common Procedure Coding System (HCPCS) is comprised of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. **Health care professionals who deliver WISEWOMAN services may be reimbursed for the procedures on this list in an amount no greater than what is reimbursed by Medicare, Part B.**

[2] The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law specified that laboratory requirements be based on the complexity of the test performed and established provisions for categorizing a test as waived. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute. CLIA-waived tests employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; pose no reasonable risk of harm to the patient if the test is performed incorrectly; and/or are cleared by the Food and Drug Administration for home use.

[3] The lifestyle intervention sessions are created to facilitate the **adoption** of health-promoting behavior for the **first time,** and maintenance activities are developed to support the **maintenance** of the behavior **over time**. Examples of maintenance activities include the provision of low-cost or free passes to community swimming pools or fitness centers; development of walking clubs; periodic mailings of newsletters or community event calendars that encourage women to practice what they have learned in the intervention sessions; and/or mailing a note of encouragement, which may include a recipe or some other healthful tip.

Appendix D

Program Announcement 03022

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03022]

Chronic Disease Prevention and Health Promotion Programs

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for Chronic Disease Prevention and Health Promotion Programs.

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A. Authority and Catalog of Federal Domestic Assistance Number

Components 1 (Tobacco), 2 (Nutrition, Physical Activity, Obesity), 4 (Oral Disease), 6 (BRFSS), and 7 (Genomics):

This program is authorized under section 301 (a) and 317 (k) (2) of the Public Health Service Act, [42 U.S.C. section 241 (a) and 247b(k) (2), as amended]. The Catalog of Federal Domestic Assistance number is 93.283.

Component 3-WISEWOMAN

This program is authorized under sections 1501-1509 [42 U.S.C. 300k-300n-4a] of the Public Health Service Act, as amended. The consolidated Appropriations Act, 2000, Public Law 106-113, also authorizes this program. The Catalog of Federal Domestic Assistance (CFDA) number is 93.283. See http://www.cdc.gov/wisewoman/legislationhighlight.htm for WISEWOMAN authorization and link to BCCEDP legislation.

Component 5 – Arthritis

This program is authorized under section 301(a) and 317(k) (2) of the Public Health Service Act, [42 U.S.C. section 241 (a) and 247b(k) (2), as amended]. The Catalog of Federal Domestic Assistance number is 93.945.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for Chronic Disease Prevention and Health Promotion Programs. This program addresses the "Healthy People 2010" focus areas of Tobacco Use, Physical Activity and Fitness, Nutrition and Overweight, Public Health Infrastructure, Oral Health, Arthritis, Osteoporosis, Back Conditions, Educational and Community-Based Programs, Cancer, Diabetes, Genomics, and Surveillance and Data Systems.

The purpose of the program is to support capacity building, support program planning, development, implementation, evaluation, and surveillance for current and emerging chronic diseases conditions.

The Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) is issuing this program announcement in an effort to simplify and streamline the grant pre-award and post-award administrative process, provide increased flexibility in the use of funds, measure performance related to each grantee's stated objectives and identify and establish the long-term goals of Health Promotion programs through stated performance measures. These efforts include incorporation of improved performance measures, enhancement of short and long term objectives, combining multiple reports, establishment of consistent reporting requirements, and advancing from one public health program funding level to a higher level based on performance.

This program announcement incorporates funding guidance for the following seven program components: Tobacco; Nutrition, Physical Activity, and Obesity; Well Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN); State-based Oral Disease Prevention; Arthritis; Behavior Risk Factor Surveillance Systems (BRFSS); and Genomics and Chronic Disease Prevention programs.

CDC encourages recipients to identify opportunities to link chronic disease and health promotion efforts across this and related program announcements, where appropriate (i.e. cardiovascular health, diabetes, genomics, tobacco, nutrition and physical activity, obesity, etc.). These efforts could include co-funding of recipient activities and cost sharing of staff time, in support of shared, overlapping objectives across program components and cooperative agreements. Such complementary activities must meet the program objectives of the funded component/program.

Your application should be submitted as one application but should consist of each separate Specific Categorical Component. Applications will be due on March 28, 2003. The categorical components and specific purposes for each are:

Component 1: Comprehensive State-Based Tobacco Prevention and Control Programs – The purpose of this program is to achieve four Program Goals through community interventions and mobilization; counter-marketing; policy development and implementation; and surveillance and evaluation. The goals are: prevent initiation to tobacco use among young people; eliminate exposure to second hand smoke; promote cessation among adults and young people who use tobacco; and identify and eliminate tobacco-related disparities among specific population groups.

Component 2: State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases – The purpose of the program is to prevent and control obesity and other chronic diseases by supporting States in the development and implementation of science-based nutrition and physical activity interventions. Major program areas are: balancing caloric intake and expenditure; improved nutrition through increased breastfeeding and increased consumption of fruits and vegetables; increased physical activity; and reduced television time. See Goals at http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm.

Component 3: Well integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) – The purpose of this program is to support health promotion efforts through the WISEWOMAN program, focusing on early detection of chronic diseases and their associated risk factors and prevention of chronic diseases through lifestyle interventions. The WISEWOMAN program promotes a healthy lifestyle through increased physical activity, improved nutrition, weight control, and smoking cessation. The target population is women aged 40-64 years old who are participants in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) comprehensive screening programs funded by the Centers for Disease Control and Prevention (CDC). Because eligibility for the NBCCEDP is based on inadequate health insurance coverage and lack of financial resources, the WISEWOMAN program aims to increase access to quality care through screening for conditions such as high cholesterol and high blood pressure using methods detailed in national clinical guidelines. Along with lifestyle interventions, medical referral and follow-up are also important components of the program.

Component 4: State-Based Oral Disease Prevention Programs – The purpose of this program is to establish, strengthen and expand the capacity of States, Territories, and tribes to plan, implement, and evaluate population-based oral disease prevention and health promotion programs, targeting populations and oral disease burden, as outlined in "Oral Health in America: A Report of the Surgeon General," and can be found using the following link http://www.surgeongeneral.gov/library/oralhealth.

Component 5: Arthritis – The purpose of this program is to assist States in developing, implementing, and evaluating State level programs to control of arthritis and other rheumatic conditions. This program emphasizes State-based leadership in coordinating State Health Department capacity to reduce the burden of arthritis within the State. Programmatic efforts should focus on persons affected by arthritis, i.e., persons already experiencing the systems of arthritis, their families, and others treating or providing services for persons with arthritis. By targeting persons affected by arthritis, prevention strategies are secondary and tertiary, focusing on prevention of disability and improving quality of life. There will be two levels of activities for this component: Capacity Building Program Level A and Capacity Building Level B. See "Recipient Activities" for specific activities for each level.

Component 6: Behavior Risk Factor Surveillance Systems (BRFSS) – The purpose of this program is to provide financial and programmatic assistance to State Health Departments to maintain and expand 1) specific surveillance using telephone survey methodology of the behaviors of the general population that contribute to the occurrence of prevention of chronic diseases and injuries, and 2) the collection, analysis, and dissemination of BRFSS data to State categorical programs for their use in assessing trends, directing program planning, evaluating programs, establishing program priorities, developing policy, and targeting relevant population groups.

Component 7: Genomics and Chronic Disease Prevention – The purpose of the program is to assist States in developing agency-level genomics leadership and coordination capacity that ensures effective planning, implementation and evaluation of knowledge and tools for using genetic risk factors and family history in improving chronic disease prevention and health outcomes. The study of genes and their function has led to recent advances in genomics and our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors. This program requires the integration of genomics and family history assessments into ongoing and new population-based strategies for identifying and reducing the burden of specific chronic, infectious and other diseases. Of particular importance is enhanced planning and coordination to integrate genomics into core State public health specialties of genomics within State core public health specialties (such as epidemiology, laboratory activities, and environmental health) and to facilitate the effective application of new knowledge, enable effective application of new knowledge about gene-environment interactions, and crosscutting family history information to chronic disease prevention opportunities.

NOTE: The following statements are applicable for all Components:

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Disease Prevention and Health Promotion (NCCDPHP): reduce cigarette smoking among youth; support prevention research to develop sustainable and transferable community-based behavioral interventions; increase the capacity of State arthritis programs to address the prevention of arthritis and its complications at the community level; help States monitor the prevalence of major behavioral risks associated with premature morbidity and mortality in adults to improve the planning, implementation, and evaluation of disease prevention and health promotion programs; support high-priority State and local disease prevention and health promotion programs, and to help State use genetic information in their public health programs.

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of effectiveness must relate to the performance goal (or goals) as stated in section "B. Purpose" of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

C. Eligible Applicants

Limited Competition

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and Federally recognized Indian tribal governments. A bona fide agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a state application.

All applications received from current grant recipients under Program Announcements 99038, Component 1, (Comprehensive State-Based Tobacco Use Prevention and Control Programs); 00115 and 99135, Component 3 (Well Integrated Screening and Evaluation for Women Across the nation WISEWOMAN) and 01098 (WISEWOMAN Enhanced); 01046, Component 4 (Support for State Oral Disease Prevention Programs); 01097, Component 5 (Reducing the Impact of Arthritis and Other Rheumatic Conditions); 99044, Component 6, (Behavior Risk Factor Surveillance systems) will be funded upon receipt and approval of a technically acceptable application. In addition to the eligible applicants above, potential applicants that are eligible for specific components 2, 3, 4, 5, 6, and 7 are:

Component 2 – State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases:

Eligibility for this component is limited to States, Territories, and the District of Columbia. Applicants can apply for either or both programs, "Capacity Building or Basic Implementation funding." Applicants awarded Basic Implementation funds will not be considered for Capacity funding. Applicants applying for both programs must submit two separate applications for this component.

Component 3 - WISEWOMAN: Assistance will be provided only to the health departments of certain States/Territories/Tribes or their bona fide agents who are currently receiving grants under Section 1501 of the Public Health Service Act. Applicants are eligible for one of two levels of funding for one of two types of projects, Standard or Enhanced (see Appendix A: Eligibility and Appendix B: Type of Program and Performance Requirements for more details).

Component 4 – State-Based Oral Disease Prevention Programs: The 13 States currently receiving CDC funds for CORE Programs under Program Announcement 01046 are eligible to apply

for Part 1 Capacity Building Program: Alaska, Arkansas, Colorado, Illinois, Michigan, New York, Nevada, North Dakota, Oregon, the Republic of Palau, Rhode Island, South Carolina, and Texas.

Current CORE Program grantees that apply for Basic Implementation Program funding in year two and are not funded will continue to receive funding for the CORE (Capacity Building) Program. To make this possible, currently funded CORE (Capacity Building) Program grantees must provide a separate CORE (Capacity Building) Program Logic Model, Work Plan, budget, and budget justifications that addresses CORE (Capacity Building) Program activities to expedite the award process.

Component 5 – Arthritis: The only eligible applicants for Capacity Building Level B Funding during year one of this program announcement are the following 28 States which are currently funded under Program Announcement 01097, Reducing the Impact of Arthritis and Other Rheumatic Conditions: Alaska, Arizona, Arkansas, Colorado, Connecticut, Idaho, Indiana, Iowa, Kentucky, Maryland, Michigan, Nebraska, Nevada, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, and Wisconsin. These States may not apply for Capacity Building Program Level A funding during year one of this announcement.

Eligible applicants for Capacity Building Program Level A are those currently funded under Program Announcement 99074 and health departments other than those listed above who meet the requirements outlined in the "Recipient Activities" section of this Component for Capacity Building Program Level B and Capacity Program Level A.

Component 6 – Behavior Risk Factor Surveillance Systems (BRFSS): Assistance will be provided only to the existing 54 health departments funded under the Behavioral Risk Factor Surveillance, Program Announcement Number 99044.

Component 7 – Genomics

Assistance will be provided only to the health departments of States or their bona fide agents. A bona fide agent is an agency/organization identified by the state as eligible to submit an application under the State eligibility in lieu of a State application.

D. Availability of Funds

Approximately $91,700,000 is available in FY 2003 to fund approximately 194 awards.

It is expected that the awards will begin on or about June 30, 2003 and will be made for a 12-month budget period within a project period of up to five years.

Pending availability of funds, beginning in year two and each of the remaining years for this program announcement (June 30, 2004 through June 30, 2008), there will be an open season for competitive applications. Specific guidance will be provided with exact due dates and funding levels each year.

Applications from all new applicants as well as all currently funded programs, whose project period have ended or will end in FY 2003, will be competitively reviewed by an independent Objective Review Panel.

Continuation awards for year two and beyond will be made on the basis of satisfactory progress made toward the attainment of the goals, objectives, and corresponding performance measures as evidenced by required reports, and based on the availability of funds. Additional information is listed on a component-by-component basis.

Component 1: Comprehensive State-Based Basic Tobacco Prevention and Control Programs

D.1. Availability of Funds

Approximately $57 million is available in FY 2003 to fund 59 awards.

In year one, States and Territories currently funded under program announcement 99038 should apply for the same base amount that is currently received on a non-competitive basis. Applicants should refer to "Recipient Financial Participation" for information on required matching funds. The remaining unfunded Territory is Marshall Island that is eligible to apply for funds in the amount of $100,000 to $125,000. If Marshall Island submits an application, it will be reviewed under a competitive review process.

Continuation award amounts may be adjusted should a State receive lawsuit settlement funds, general funds, or excise tax funds for the State's comprehensive program.

Use of Funds:

CDC funds cannot be used to supplant existing State funding. Applicants may not use these funds to supplant funds from Federal or State sources, the Preventive Health and Health Service Block Grant or Center for Substance Abuse Prevention funding for youth access enforcement. Applicants must maintain current levels of support dedicated to tobacco use prevention and control from Federal, State sources, or the Preventive Health and Health Services Block Grant.

Funds may not be used to conduct research. Surveillance and evaluation activities are for the purposes of monitoring program performance, and are not considered research.

Cooperative agreement funds must be used for focused strategies to change systems, develop and implement policies, change the environment in which tobacco use occurs, and impact population groups rather than individuals. To this end, cooperative agreement funds may not be used to provide direct services such as individual and group cessation services, patient care, personal health services medications, patient rehabilitation, or other costs associated with the treatment of diseases caused by tobacco use. Funds may be used to support activities in line with CDC "Guidelines for School Health Program to Prevent Tobacco Use and Addiction" including curricula but may not be used for staff time to provide direct classroom instruction of students. Cooperative agreement funds may not be used to directly enforce tobacco control policies unless there are extenuating circumstances within the State. A justification must be provided and reviewed.

Recipient Financial Participation

Federal sources as follows. During the first year of the award, States receiving funding from another source(s) that is equal to or greater than the CDC award will match one dollar of direct cash match from non-Federal sources for every dollar of Federal funds. All other States and Territories that do not receive funds from non-Federal sources that are equal to or greater than the CDC award will provide one dollar of cash or in-kind match from non-Federal sources for every ten dollars of Federal funds.

Beginning in the second year and in each subsequent year of the award, all States and Territories will provide one dollar from non-Federal sources for every four dollars of Federal funding. The match may be cash, in-kind, or a combination from State and/or public and private sources.

Technical assistance will be available for potential applicants through the following means: a minimum of two conference calls to be held on or around December 12, 2002 and January 10, 2003.

E.1. Program Requirements

In conducting activities to achieve the purpose of this program component, the recipient will be responsible for the activities under "1. Recipient Activities," and CDC will be responsible for the activities listed under "2. CDC Activities."

1. Recipient Activities

a. Program Management

Identify and hire staff with the appropriate competencies to manage a tobacco prevention and control program and provide information to demonstrate that management staff are at a level within the agency to affect the decision making process related to the tobacco program.

A suggested minimum number of staff would be seven FTEs including one FTE Program Manager and one FTE for administrative support. Staff should have knowledge and skills in: program development, coordination and management; fiscal management including management of funding to State and local partners; leadership development; tobacco control and prevention content; cultural competence; public health policy including analysis, development and implementation; community outreach and mobilization; training and technical assistance, health communications including counter-marketing; strategic use of media including media advocacy, earned and paid media; strategic planning; gathering and analyzing data (surveillance); and evaluation methods.

Funding from other sources increases the scope of the program, requiring additional staff to administer and monitor the program. A suggested number of staff based on increased funding levels would be an additional one to eight FTEs for a total of eight to sixteen FTEs with program justification including description of activities funded through other sources. The Program Manager and the administrative support position should be FTEs within the State Health Department (SHD). Other positions may be SHD FTEs or may be contractual.

Performance will be measured by evidence that the SHD has dedicated human resources to administer and manage the program effectively that is consistent with the competencies and staffing levels identified above in item (a) "Program Management."

Evidence of the provision of ongoing training for staff can be demonstrated through staff participation in CDC sponsored training, meetings and conferences and other continuing education opportunities as identified by SHD program staff.

Evidence of organizational impact could be demonstrated by providing evidence that management staff have organizational access to the State Health Officer and by providing information to support senior level management involvement in the tobacco program.

b. Fiscal Management

1. Describe how funding to support State and local programs that focus on population-based strategies, are science-based and policy-focused, and reach diverse groups will be accomplished.

2. Track and monitor the health and economic burden of tobacco use in the State through surveillance and evaluation activities, program activities supporting goals and objectives, tracking policy development and implementation.

Performance will be measured by evidence that the SHD activities resulted in accomplishment of items (a) through (d) above.

c. Strategic Planning

Develop a five-year strategic plan with active participation of State and local partners. The strategic plan should reflect all tobacco prevention and control activities in the State. It should be linked to and complement the SHD comprehensive cancer control plan, the cardiovascular health plan and other SHD plans to reduce tobacco-related chronic diseases. The five-year strategic plan should include: Description of evidence-based program and policy strategies tailored to data determined State needs; a logic model linking activities to outputs and short-term and intermediate outcomes using specific, measurable, achievable, relevant, and time bound program objectives; program evaluation activities including a summary and time-line for data collection activities; program components that address counter-marketing and strategic use of media advocacy and paid media when appropriate); strategies to address the four program goal areas.

Performance will be measured by evidence that a five-year basic implementation, strategic State tobacco control plan has been developed and will be updated based on environmental changes. Evidence can be shown by a description of how the plan was developed and the submission of a plan that is consistent with the activities described above in item (a) "Strategic Planning."

d. Surveillance and Evaluation

Develop and implement a basic implementation evaluation plan with stakeholder's involvement. The evaluation plan should include clear goal-based logic models, with outputs, short, intermediate, and

long-term objectives; data collection on key tobacco-related indicators using valid methods that are comparable across States; data collection timetables, the production and dissemination of evaluation reports and establishment of a method to track the number and type of policy and systems changes that promote cessation. References U.S. HHS CDC "Introduction to Program Evaluation for Comprehensive Tobacco Control Programs, November 2001" and the upcoming report on key indicators that can be used to monitor and evaluate State level tobacco control programs (expected publication date: Spring 2003) for additional information.

Performance will be measured by accomplishment of the activities described above in item (a) "Surveillance and Evaluation" and by providing the following evidence: A description of a comprehensive evaluation plan, including the involvement of stakeholders in the evaluation planning process; recommendations made and/or actions taken by an advisory group or task force composed of diverse State and local representation; a description of the data collection activities, including methodologies and data analysis; a description of process and outcome objectives and indicators to be used in program evaluation; a description of the SHD's role in coordinating surveillance and evaluation efforts and providing technical assistance and training on program monitoring, data collection, and evaluation; the production of useful evaluation reports, and the utilization of evaluation findings to improve, expand, or maintain the tobacco control program.

e. Collaboration and Communication with Partners

Develop and maintain Statewide and local active partnerships that support the goal of reducing or eliminating the health and economic burden of tobacco use and an effective communication system with partners at the State and local level. Partnerships may include Statewide and local organizations, voluntary health organizations, universities, local health departments, organizations that represent diverse communities, community based organizations, Statewide and local coalition, and boards commissions, and advisory groups with responsibility for the State Tobacco Control Program. Working with partners includes capacity building with those organizations through technical assistance, training and educational activities.

Performance will be measured by accomplishment of the activities described above in item (a) "Collaboration and Communication with Partners" and by providing the following evidence: Submission of letters of support that clearly define the level of commitment from the organization; description of grants, contacts, and memoranda of understanding; membership lists; active participation in meetings; clear role definitions for partners; active participation in Statewide and local planning including media campaigns, tobacco control plans, and conference. Evidence can be shown by: Description of stakeholder communication plan which employs multiple channels including Statewide list serve; Statewide conference, trainings, and information exchanges; electronic newsletters and updates; Statewide teleconferences; Web site postings; site visits; and videos.

f. Local Grant Programs

Support local programs to establish grassroots networks at the community level. Support should be sufficient for designated staff at the local level to establish and participate in local coalitions, partnerships, and task forces for local policy development and implementation; local environmental

scan; development and implementation of a written plan to work toward policy goals and participation in State participation in State evaluation and data collection efforts; access to tobacco control information through a variety of sources such as journals, Internet Web sites and list serves. Refer to U.S. HHS, CDC "Best Practices for Comprehensive Tobacco Control Programs-August 1999," and American Journal of Preventive Medicine "Community Prevention Services Guidelines for Tobacco Use, February 2001" for information about local programs.

Performance will be measured by accomplishment of the activities described above in item (a) "Local grant program."

g. Training and Technical Assistance

Develop and implement a technical assistance and training process to address the needs of local health department staff, coalitions, and partners involved in tobacco prevention and control activities.

Performance will be measured by evidence that training and technical assistance needs have been assessed and provided by the State Tobacco Control Program to local health department staff, coalitions, and partners. Evidence can be shown by: the number and description of trainings planned and/or provided that include the strategic purpose of the trainings and anticipated impacts as related to short-term and long-term outcomes, description of the process and strategy to provide technical assistance.

h. Prevent Initiation of Tobacco Use Among Young People.

Develop and implement science-based policy-focused strategies identified in the State strategic plan to prevent youth initiation of tobacco use.

Performance will be measured by accomplishment of the activities described above in item "(a) Prevent Initiation to Tobacco Use Among Young People." Evidence can be shown by describing: multi-component community interventions to reduce youth initiation that are science-based and policy focused such as price increase for tobacco products; educational activities that address the efficacy of policy initiatives such as restrictions on tobacco advertising, promotion and sponsorships and retailer licensing regulations; tobacco-free school policies school policies; identification of disparities related to youth initiation to tobacco use; partnerships with State and local education organizations to promote CDC "Guidelines for School Health Programs to Prevent Tobacco Use and Addiction;" Counter-marketing strategies that include media advocacy and paid advertising to disseminate messages regarding youth access; pro-health messages; State evaluation and data collection efforts to demonstrate local programs toward policies to reduce youth initiation.

i. Eliminate Exposure to Second Hand Smoke

Develop and implement science-based policy-focused strategies to reduce exposure to second hand smoke.

Performance will be measured by accomplishment of the activities described above in item (a) "Eliminate Exposure to Secondhand Smoke." Evidence can be shown by describing: Local coalition objectives and evidence-based activities that are linked to a policy change leading to short-term and long-term outcomes as identified within the State plan; counter-marketing strategies that are supportive of local policy efforts, including both earned and paid media and the numbers of people reached through earned and paid media strategies; recommendations made and/or actions taken by an advisory group or task force composed of diverse State and local representation; a description of disparities related to exposure to secondhand smoke and strategies to reduce those disparities; actions taken to expand policy coverage to new communities and/or to strengthen policies in communities where they are already in place. Evidence can also be shown by a State-specific database that tracks local clean indoor air ordinances work, where pre-emption exists, voluntary policies and reporting of the number of policies implemented; State evaluation and data collection efforts to demonstrate local progress toward policies to eliminate exposure to secondhand smoke.

j. Promote Cessation Among Adults and Youth

Implement science-based policy-focused strategies as defined in the State strategic plan to promote cessation among adults and youth.

Performance will be measured by accomplishment of the activities described above in item "(a) Promote Cessation Among Adults and Youth." Evidence can be shown by describing: Strategies to promote guidelines published in "U.S. DHHS Public Health Services Treating Tobacco Use and Dependence" and "Community Prevention Services Guidelines for Tobacco Use;" strategies to reduce identified disparities; counter-marketing strategies that incorporate earned and paid media to provide information about and motivation for quitting and reach diverse populations and the number of people reached with paid media; Statewide activities, as detailed in the State strategic plan, to promote effective methods for quitting including support for and promotion of policy development and initiatives related to cessation services; links between the State program and other organizations to support and promote cessation.

k. Identify and Eliminate Tobacco-related Disparities among Specific Population Groups

Identify and eliminate disparities in specific population groups related to 1) preventing initiation among young people; 2) eliminating exposure to secondhand smoke; and 3) promoting cessation among adults and youth.

Performance will be measured by accomplishment of activities in item (a) "Identify and eliminate tobacco-related disparities among specific population groups." Evidence can be shown by: Assessing national data sources and research related to at-risk populations; outlining demographics reflecting Statewide diversity; coordinating available State and national data with at-risk populations in the State; augmenting State data with qualitative data (i.e. population assessments of specific population groups); examining the potential limitations of data used; identifying and developing new quantitative and qualitative-based methodologies for data collection among specific population groups, developing strategies and initiatives to build capacity and infrastructure among disparately-affected population

groups. If States have participated in the Office on Smoking and Health's Disparities Pilot Training, additional evidence can be shown by demonstrating the implementation of interventions based on strategic plan to identify and eliminate tobacco-related disparities developed by a diverse and inclusive workgroup.

1. Information exchange

Develop and implement mechanisms to facilitate information exchange between the State Tobacco Control Program, the CDC, tobacco control program personnel in other States, and national partners.

Performance will be measured by accomplishment of the activities described above in item (a) "Information Exchange."

Evidence can be shown by: Establishing a communication loop with CDC for the exchange and dissemination of information about program effectiveness, progress toward short and long-term objectives as defined in the strategic plan; participation on CDC sponsored workgroups/task forces and the frequency of that participation, number of presentations at national meetings and conferences, number of publications of data and evaluation outcomes via "Morbidity and Mortality Weekly Report" (MMWR), peer-reviewed journals or as reports, number of reports on collaboration with programs and partners in neighboring States; posting information and resources on the CDC State forum; participation with Association of State Territorial Health Officers (ASTHO) regional networks and Tobacco Control Resource council and/or other tobacco-related projects sponsored by ASTHO.

2. CDC Activities

a. Provide ongoing guidance, consultation, technical assistance, and training in tobacco use prevention and control as described under "Recipient Activities."

b. Provide up-to-date information that includes diffusion of best practices for tobacco use prevention and control.

c. Provide resources and technical assistance to develop and improve monitoring and surveillance systems. Provide guidance to States to identify indicators that can be used to monitor and evaluate State level tobacco control programs.

d. Facilitate adoption of effective practices among grantees and other partners through workshops, conferences, training sessions, electronic and verbal communications.

e. Identify, develop, and disseminate media campaign materials for use by programs; facilitate coordination of counter advertising materials between programs; provide technical assistance on design, development, and evaluation of media.

f. Maintain an electronic center for State information sharing, State Forum, and the Chronicle, for progress reporting.

g. Develop and maintain partnerships with Federal and non-Federal organizations to assist in tobacco control and create a national infrastructure to complement State infrastructure.

h. Serve as a resource to States with regard to identifying and eliminating tobacco-related disparities among population groups.

i. Maintain a Web site with access to a data warehouse that contains comparable measures of tobacco use prevention and control from different data sources.

F.1. Content

The program announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative for this component, including the Executive Summary, should be no more than 45 double-spaced pages, printed on one side, with one-inch margins, and unreduced 12-point font. The annual action plan may be 20 pages, which will allow a total of 65 pages for the application (excluding budget and appendices). Appendices should total no more than 20 pages, excluding letters of support and the budget.

Focus the application content ONLY on the planned "Recipient Activities" for which you seek CDC funding. However, the Background and Need content should describe accomplishments regardless of funding source. Include a description of why CDC funding is needed and how these funds will be used strategically to complement other funding sources.

Provide supporting documentation such as resumes, job descriptions, and descriptions of coalitions and committees as appropriate. All materials must be suitable for photocopying.

1. Executive Summary

Provide a narrative, not to exceed two pages and summarize: The environment in which tobacco control has been conducted, including barriers and supportive factors; accomplishments; anticipated needs; plans to address the Program Goals. Indicate major areas of future program focus.

2. Program Narrative

Provide a narrative, not to exceed 43 pages, describing the burden of tobacco use, accomplishments to date, and areas of unmet needs. Provide specific reference to the following elements of State health department tobacco control program.

a. Background and Need

Describe the burden of tobacco use including prevalence rates and the economic costs of tobacco use. Describe existing policies at the State and local level. Describe progress toward reducing the burden of tobacco use. Describe major tobacco control activities conducted in the State and how CDC funds will enhance these programs as well as other chronic disease and health promotion areas.

Describe, if applicable, the impact of State budget cuts on program priorities and activities that will not be accomplished.

b. State Health Department Infrastructure and Program Management

Describe current staff. Describe plans to develop a staffing pattern consisting of qualified technical, program, and administrative staff that are diverse and representative of the State population. Describe how program staff will have access to opportunities for professional training. Describe how the staffing pattern will enable sharing of information, resources, and materials with CDC and the national program. Describe how involvement of senior management and communication with the State Health Officer will be assured.

3. Organization

Provide an organizational chart showing placement of the tobacco control program within the organization, indicating accountability and lines of communication.

4. Fiscal Management

Describe plans to fill vacancies to minimize start-up delays, assure out of State travel, and administer funds to governmental and non-governmental entities at the State and local level. Describe accomplishments and barriers in providing funding to support State efforts. Describe accomplishments and barriers in providing funding to support State efforts. Describe accomplishments and barriers in filling staff vacancies, supporting out-of-State travel, and reducing start up delays. Describe a plan for maintaining adequate staffing to administer the program should budget cuts, hiring freezes, etc. occur.

5. Strategic Plan

Provide a copy of the five-year comprehensive strategy that meets the criteria in Recipient Activities (2) Strategic Planning and describe how the plan was developed based on the process in Recipient Activities

(2). Demonstrate how the plan links to and compliments the SHD's comprehensive cancer control plan, the cardiovascular health plan, and other SHD plans to reduce tobacco-related chronic diseases. If a comprehensive strategic plan does not currently exist, describe how a plan will be developed and the expected completion date. Describe the process by which the strategic plan will be updated. Indicate who will be responsible for maintaining the plan.

6. Surveillance and Evaluation

Describe accomplishments. List the tracking systems used and/or needed at the State and local levels. Describe surveillance and evaluation activities currently being undertaken. Refer to U.S. HHS CDC "Introduction to Program Evaluation for Comprehensive Tobacco Control Programs, November 2001." Describe involvement of stakeholders or advisory group in development of

surveillance and evaluation approach. Describe barriers and identify methods to overcome them. Describe unmet needs and plans to address them.

7. Collaboration and Partnerships

Describe plans to develop, strengthen and maintain partnerships and coalitions through linkages with other national, regional, State, and local level governmental, and non-governmental entities. Specify partner organizations and the purpose of those partnerships. Describe current State coalition members and plans to recruit new members. Describe plans to identify new partners including proposed partners and purpose of partnerships. Describe plans to maintain and strengthen participation by groups identified as experiencing tobacco related health disparities.

Describe plans to collaborate with CDC and other Federal agencies, including participation in national or regional meetings and workgroups, and using the Internet to communicate and disseminate information.

Describe how the State's and partners' roles will complement each other as part of the overall effort. Provide letters of support demonstrating collaborative activities, roles, responsibilities, and/or commitment of funds or other resources.

Describe communication methods and channels used to inform and solicit information from stakeholders.

Describe how the stakeholder communication plan was developed. Describe barriers in communicating with stakeholders. Describe plans to improve communication.

8. Local Grant Programs

Describe existing local grants programs including funded organizations and level of funding, policy-focused activities, and collaboration with partners, and participation in coalitions. Describe the rationale for funding local organizations. Describe local environmental scans and how the scans inform a planning process. Describe progress toward policy goals and objectives. Describe how personnel access tobacco control information. Describe barriers and methods to address them. Describe unmet needs and plans to address them. If a local grants program does not currently exist, describe how such a program will be developed and implemented, including a timeline for implementation, a description of the grant process and eligible organizations.

9. Training and Technical Assistance

Describe the audiences for whom training and technical assistance is provided. Describe how training and technical assistance needs will be determined. Describe activities and how they contribute to advancing the program goals and objectives. Describe barriers and methods used to overcome them. Identify unmet needs and plans to address them.

10. Prevention Initiation of Tobacco Use Among Youth

Describe activities at the State and local level, including activities that are science-based and promote policy interventions. Describe activities to promote tobacco-free policy in schools. Describe surveillance and evaluation activities. Describe barriers and identify methods to overcome them. Describe unmet needs and plans to address them.

11. Eliminate Exposure to Secondhand Smoke

Describe activities to move toward policy development at the local level, identify and eliminate disparities, collect and analyze data, conduct counter-marketing.

Describe activities undertaken by State and local coalitions/task forces and partnerships. Describe barriers and identify methods to overcome them. Describe unmet needs and plans to address them.

12. Promote Cessation for Adults and Youth

Describe activities and strategies to promote science-based cessation services and policies. Applicants should refer to the "Community Prevention Services Guidelines for Tobacco Use" and "U.S. DHHS Public Health Services Treating Tobacco Use and Dependence."

Describe disparities and strategies to reduce them. Describe methods used to promote and encourage cessation including counter-marketing, policy development, and implementation, and population-based and systems change strategies. Describe barriers and methods to overcome them. Describe unmet needs and plans to address them.

13. Identify and Eliminate Tobacco-Related Disparities in Specific Populations

Describe the process for identifying and eliminating tobacco-related disparities. Include a description of: the national and/or State data sources used; the State population demographics; rationale for addressing tobacco-related disparities in specific population groups; specific strategies and initiatives to build capacity and infrastructure among disparately-affected population group. Describe the process for developing a strategic plan, if one exists, including who was involved and progress in implementation. Attach a copy of the plan.

14. Information Exchange

Describe how State personnel communicate and exchange information with Federal, regional, State, and local tobacco control personnel in government and partner organizations. Describe participation in and collaboration with State and national organizations. Describe participation in local, State, regional, and national conferences and meetings and the benefits accrued. Describe barriers and identify methods to overcome them. Describe unmet needs and plans to address them.

15. Annual Action Plan (no more than 20 pages)

Submit an annual action plan detailing how the above requirements will be addressed. Include objectives with indicators and data sources. When writing long-term, intermediate, short-term, and annual objectives, use specific, measurable, achievable, relevant, and time-bound (SMART)

objectives. For each of the four program components in the Annual Action Plan, indicate key activities. For each activity, include the target group, lead role, timeline, and anticipated output. The Annual Action Plan: Program Goals form can be used to complete this requirement and will be provided at the pre-application workshop.

16. Budget and Accompanying Justification (no page limit).

Provide a line-item budget and justification consistent with the stated objectives, planned activities, and time frame of the project. Identify matching funds. Matching funds may be cash, in-kind or donated services or a combination of these made directly or through donations from public or private entities. All costs used to satisfy the matching requirements must be documented by the applicant.

Commit a minimum of 10 percent of award to surveillance and evaluation efforts. Program resources may be used for consultants; staff, survey design and implementation, data analysis, or other expenses associated with surveillance and evaluation efforts. These activities may fulfill the match requirement.

A maximum of five percent of the award may be used to directly support a statewide telephone cessation counseling service with program justification.

Include travel for a minimum of three staff members or selected representatives to attend each of two CDC-sponsored training meetings per year, one staff person to attend a media training, a minimum of two staff people to attend one CDC-sponsored Program Management meeting, a minimum of two staff people to attend a training on the NTCP Chronicle, and a minimum of two staff people to attend the CDC-sponsored national tobacco control conference. For purposes of planning, these meetings/conferences should be budgeted for travel to Atlanta, Boston, and Phoenix.

Meeting	# of Staff	Location
CDC sponsored training meeting (surveillance and evaluation)	3	Atlanta, GA
CDC sponsored media training	1	Atlanta, GA
OSH Program managers meeting	2	Atlanta, GA
OSH NCTP Chronicle training	2	Atlanta, GA
CDC sponsored national training program	3	Phoenix, AZ
CDC sponsored national tobacco control conference	2	Boston, MA

States and Territories can request that CDC cover the travel costs of out-of-State trainings and meetings for one staff person per required meeting or conference. If a State program elects to have CDC cover travel costs, clearly state that the program is electing this option and provide an estimated expense for travel. Under this arrangement, the State award will be reduced by the amount estimated for travel plus an additional administrative cost.

G.1. Evaluation Criteria

Application

Applications received from current grantees that are funded under Program Announcement 99038 will be reviewed utilizing the Technical Review process. Total possible points equal one hundred. Total points = 100

a. Background and Need (12 points)

The extent to which the applicant describes Background and Need in Application Content, 2a.

b. Annual Action Plan (11 points)

The extent to which the annual action plan is based on the strategic plan and include activities in line with Recipient Activities and Application Content for tobacco control program.

c. Program Management (7 points)

The extent to which the applicant describes specific Recipient Activities in section 1a-d above and activities in Application Content, 2b.

d. Strategic Plan (7 points)

The extent to which the applicant has addressed specific Recipient Activities in Section (2); and Application Content, b 5.

e. Surveillance and Evaluation (7 points)

The extent to which the applicant clearly describes specific Recipient Activities in Section (3); and Application Content, b 6.

f. Collaboration and Communication with Partners (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (4a); and Application Content, b 7.

g. Local Grant Programs (7 points)

The extent to which the applicant describes specific Recipient Activities, Section (5); and Application Content, b 8.

h. Training and Technical Assistance (7 points)

The extent to which the applicant demonstrates specific Recipient Activities in Section (6); and Application Content, b 9.

i. Prevent Initiation to Tobacco Use Among Young People (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (7a); and Application Content, b 10.

j. Eliminate Exposure to Secondhand Smoke (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (8a); and Application Content, b 11.

k. Promote Cessation Among Adults and Young People (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (9a); and Application Content, b 12.

l. Identify and Eliminate Tobacco-Related Disparities Among Specific Population Groups (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (10a); and Application Content, b 13.

m. Information Exchange (7 points)

The extent to which the applicant describes specific Recipient Activities in Section (11) and Application Content, b 14.

n. Executive Summary (not scored)

The extent to which an overview of the program is provided in a clear and concise manner.

Component 2: State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases

D.2. Availability of Funds

Approximately $7,000,000 is available in FY 2003 to fund approximately 16 State program awards for this component. Approximately $2,000,000 is available to fund one to two Basic Implementation Programs; approximately $5,000,000 is available to fund twelve to fourteen Capacity Building Programs. The average Capacity Building Program award will be $400,000 ranging from $350,000

to $450,000. The average Basic Implementation Program award will be $700,000 in year one ranging from $600,000 to $800,000.

Use of Funds

Funds awarded under this component of this program announcement may not be used to supplant existing State or local funds. Cooperative agreement funds may be used to support personnel and to purchase equipment, supplies, and services directly related to program activities and consistent with the scope of the cooperative agreement. Cooperative agreement funds cannot be used to provide patient care, health screening, personal health services, medications, patient rehabilitation, or other costs associated with the treatment of obesity and chronic diseases. Population-based behavioral interventions are acceptable.

Recipient Financial Participation

Recipient financial participation (matching funds) is required for only Basic Implementation programs in accordance with this Program Announcement. If applying for Basic Implementation programs, matching funds are required from non-Federal sources in an amount not less than one dollar for each four dollars. The matching funds may be cash or its equivalent in-kind or donated services, fairly evaluated. The contribution may be made directly or through donations from public or private entities.

Matching funds may not be met through: (1) the payment of treatment services or the donation of treatment, or direct patient education services; (2) services assisted or subsidized by the Federal Government; or (3) the indirect or overhead of an organization. Matching funds must be consistent with the work plan activities that are submitted and approved.

E.2. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1.a. (Recipient Activities for Capacity Building Program) or 1.b. (Recipient Activities for Basic Implementation Programs) and CDC will be responsible for the activities listed under 2. (CDC Activities).

The focus of this program component is implementation of nutrition and physical activity strategies for health promotion for the entire population and for the prevention and control of obesity. Major program areas are: obesity prevention and control including balancing caloric intake and expenditure; improved nutrition including increased breastfeeding and increased consumption of fruits and vegetables, increased physical activity; and reduced television time. For all capacity building and basic implementation program recipient activities, efforts to address poor nutrition and physical inactivity should be coordinated with State Health Agency programs in cardiovascular health, cancer, diabetes, oral health, maternal and child health (including breastfeeding), arthritis, and WISEWOMAN, as well as with the State Agriculture Agency, and coordinated school health programs in the State Education Agency (see http://www.cdc.gov/nccdphp/dash/cshpdef.htm for a description of a coordinated school health program), and other relevant State Agencies.

1.a. Recipient Activities for Capacity Building Programs

NOTE: As part of this program component, detailed descriptions of the program and additional information related to Capacity Building and Basic Implementation programs are located in "Technical Assistance Manual for State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases" at

http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm.

The referenced Web site information will assist you in addressing the details of the recipient activities when completing your application.

(1) Develop a Coordinated Nutrition and Physical Activity Program Infrastructure.

Provide indicators of sound program infrastructure including program staff placed high in the organization to coordinate the program with other related programs, high level administrative commitment to sustain the program, access to resources such as physical space, funding, and training, access to scientific resources such as subject matter specialists and surveillance resources, and broad partnerships to institutionalize nutrition and physical activity. Examples of coordination include shared positions; joint planning, and combined strategy development and implementation. Organizational location of the program is recommended to be in the agency's chronic disease or health promotion section so that this program is aligned with chronic disease programs, such as cardiovascular health and diabetes, to allow for maximum collaboration. (See referenced Web site above).

(a) Staffing

Identify, hire, or reassign, and supervise at least three dedicated full-time staff with appropriate competencies to plan and implement the program (major program areas: Obesity prevention and control including caloric intake and expenditure, improved nutrition including increased breastfeeding and increased consumption of fruits and vegetables, increased physical activity, and reduced television time). Staff includes a full-time high-level program coordinator to coordinate the crosscutting nutrition and physical activity functions for health department programs and other partners, a full-time physical activity coordinator, and a full-time nutrition coordinator. Staffing patterns are encouraged to include program skills and expertise necessary to carry out the program. Part of staff capacity building must be in 5 A Day fruit and vegetable promotion efforts.

(b) Training

Participation in training, conferences, and frequent communication with national and State collaborators including other funded States.

(2) Collaborate and coordinate with State and local government and private partners, including members of the population throughout the planning process. (See referenced Web site above).

(a) Develop new linkages and maintain collaborations with State and local partners to coordinate nutrition and physical activity efforts, especially State Health Agency programs in cardiovascular health, cancer, diabetes, oral health, maternal and child health (including breastfeeding), arthritis, and WISEWOMAN, as well as the State Agriculture Agency, coordinated school health in the State Education Agency, and other relevant State Agencies. State programs should serve as a training and technical assistance resource for local health departments and others to conduct nutrition, physical activity, and obesity prevention interventions.

(b) Collaborate with Prevention Research Centers, academic partners, and other relevant organizations in the State.

(3) Conduct a planning process that leads to a comprehensive nutrition and physical activity plan to prevent and control obesity and other chronic diseases, and start to implement the plan. (See referenced Web site above.)

(a) Describe the obesity epidemic and other chronic diseases in the State related to poor nutrition and physical inactivity.

(b) Describe the nutrition and physical activity risk factors associated with obesity and other chronic diseases.

(c) Describe the population subgroups affected by obesity that will be targeted for interventions.

(d) Conduct inventories of strategies and programs currently used in the State to prevent or control obesity and other chronic diseases in one or more settings, such as worksite, faith-based organizations, health care services, or communities.

(e) Establish priorities with and for the subgroups; identify the behaviors and influences of the population subgroups which are priorities for intervention.

(f) Use the social-ecological theoretical model to guide State planning to address obesity and other chronic diseases in these populations; select and implement interventions from the list of proven strategies at

http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm so that multiple levels of influence in the social-ecological model are addressed. Consider using a social marketing approach in the intervention.

(g) With key stakeholders, write the comprehensive State plan for nutrition and physical activity for the State, not just for the State Department of Public Health. One reference document to consider when developing the plan is the "Guidelines for Comprehensive Programs to Promote Healthy Eating and Physical Activity" at http://www.astphnd.org. Documents guiding coordinated school health programs are at http://www.cdc.gov/nccdphp/dash/.

Design the plan to address nutrition and physical activity needs of the population including the pediatric population. The State plan should address at a minimum the following major program

areas: Obesity prevention and control including caloric intake and expenditure, improved nutrition including increased breastfeeding and increased consumption of fruits and vegetables, increased physical activity, and reduced television time.

Include descriptions of how the State Health Department will work with the State Education Agency to address nutrition and physical activity needs of the population through school programs.

(h) Begin to implement components of the comprehensive State plan for nutrition and physical activity by year two.

(4) Identify and assess data sources to define and monitor the burden of obesity.

Strengthen capacity to assess the burden of obesity and the impact of the program to change overweight and obesity related behaviors, particularly nutrition and physical activity. Data systems should monitor trends, disseminate data/information, and support evaluation efforts. Monitor at minimum, body mass index (BMI), BMI-for-age, and dietary and physical activity behaviors. Data sources may include established surveillance systems (e.g., the Behavioral Risk Factor Surveillance System [BRFSS], Pediatric Nutrition Surveillance System, Pregnancy Nutrition Surveillance System, and Youth Risk Behavior Surveillance System) or alternative sources. Include a review process of considering potential changes needed in current surveillance systems and designate who is responsible for implementing and maintaining the surveillance system. (See referenced Web site above.)

CDC will work with States to develop standard measures/indicators, and States will need to adopt these standardized measures. States are encouraged to retain flexible systems that can be modified as needed.

(5) Implement and evaluate an intervention to prevent obesity and other chronic diseases. (Complete between years two to five.)

Address one or more of the major program areas from the State plan in the intervention: Obesity prevention and control including caloric intake and expenditure, improved nutrition including increased breastfeeding and increased fruit and vegetable consumption, increased physical activity, and reduced television time. Provide a balance between nutrition and physical activity related interventions. Consider using a social marketing approach in the intervention. Specify clear, measurable process and impact objectives, and outcome objectives where feasible. Programs are encouraged to approach change at the State, community (towns, cities, counties, or regions), organizational (e.g., worksites), and group level (e.g., families). (See referenced Web site above.)

(6) Evaluate progress and impact of the State plan and intervention projects.

Develop an evaluation plan that includes baseline data and intermediate outcomes for the State plan's objectives. CDC has developed a plan for evaluating the State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases based on a logic model framework. State evaluation plans should include issues addressed in the national evaluation plan as well as specific State program components.

1.b. Recipient Activities for Basic Implementation Programs.

Basic Implementation programs will expand their efforts to fully implement the State plan by enhancing surveillance activities, implementing Statewide interventions, funding communities to implement interventions, rigorously evaluating a new or existing intervention, and enhancing partnership efforts particularly with coordinated school health programs in the State Education Agency and with secondary prevention partners. In addition to providing evidence of and enhancing the Recipient Activities for Capacity Building Programs, Activities 1-6, Basic Implementation programs will address the follow activities.

(1) Expand the existing coordinated nutrition and physical activity program infrastructure.

(Year One) Expand staffing beyond the capacity building program to fully implement the State plan. Support and expand the program infrastructure at the local/regional level throughout the State.

(2) Implement the State comprehensive plan for nutrition and physical activity and review and update the plan periodically. Develop and provide mini-grants and other assistance to support communities to adopt effective interventions. (Years One-Five)

Assure that there is a continuing focus on strategic planning to reach objectives agreed upon within the State and to respond to new challenges and events. Review the written State plan annually. Adopt and diffuse effective interventions statewide or in communities and populations based on the State plan. Select and implement interventions from proven strategies so that multiple levels of influence in the social-ecological model are addressed, as guided by the State plan. Interventions can target the full State or local populations. Implement the "Community Guide to Preventive Services" physical activity recommended interventions in more depth or in more communities. Build community capacity to carry out and sustain an effective nutrition program. Provide intervention mini-grants to communities. Basic implementation programs located in States with CDC-funded coordinated school health programs must include a school-based intervention, working closely with the State Education Agency.

(3) Expand partnerships with State Health Department units, the State Education Agency, other State agencies, local communities, and private partners to maximize impacts of the basic implementation program. (Years One-Five)

Leverage resources for nutrition and physical activity working with the health department director, other health department units, the State Education Agency, other State agencies that share mutual goals, and other partners including local health partners and community groups. Identify environmental and policy issues; promote optimal standards and practices for nutrition and physical activity programs; and increase capacity through shared resources and expertise.

(4) Develop a new or apply an existing intervention and evaluate its effectiveness to prevent or control obesity and other chronic diseases every five years. Provide a balance between nutrition and physical activity interventions. Basic implementation programs should design the intervention project to detect realistic changes in post-intervention outcome measures when compared with pre-intervention measures. Sample sizes should provide adequate power to detect these changes. Specify

clear, measurable evaluation objectives using process, impact, and outcome objectives. Intervention protocol development, project evaluation, and the preparation of publications and presentation of findings should be done in collaboration with community partners, Prevention Research Centers, university affiliates, relevant experts, and CDC, as appropriate.

(5) Collaborate with partners on secondary prevention strategies. (Years One-Five)

Describe activities supporting secondary prevention related to obesity. Integrate secondary prevention strategies and activities into the State plan, partnerships, policy and environmental changes, and training for health professionals to ensure that recognized national guidelines are followed. (See http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm for additional information regarding this activity.)

(6) Develop resources and training materials to help other State and local projects adopt successful programs.

(Years Four-Five)

Develop one or more training reports on at least one component of a program that works and train staff from other State or local programs. Assist in the dissemination and training of other State and local partners regarding the report findings. (See http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm for additional information regarding this activity.)

(7) Identify, assess, or develop data sources to further define and monitor the burden of obesity.

See previous description of this activity under Capacity Building Recipient Activity 4.

(8) Evaluate progress and impact of the State plan and intervention projects.

See previous description of this activity under Capacity Building Recipient Activity 6.

2. CDC Activities

a. Convene workshop and/or teleconferences of recipient programs for information sharing and problem-solving.

b. Provide ongoing guidance, consultation, and technical assistance to plan, implement, and evaluate all aspects of nutrition and physical activity program activities. Activities include coordinating national surveillance activities, monitoring data quality of national surveillance systems, assisting with analyses and interpretation of findings from qualitative and quantitative research; assisting in the social marketing process, guiding program evaluation, and sharing community, environmental and policy strategies to promote physical activity and healthy eating. Disseminate to recipients relevant state-of-the-art research findings and public health recommendations related to obesity and other chronic disease prevention and control through nutrition and physical activity interventions.

c. On a consultant basis, assist in the development and review of the intervention protocols and program evaluation methods.

d. Coordinate national level partnerships with relevant organizations and agencies involved in the promotion of physical activity and nutrition for the prevention and control of obesity and other chronic diseases.

NOTE: Special Guidelines for Technical Assistance Telephone Conference Call

Technical assistance will be available for potential applicants on one conference call. Potential applicants are requested to call in using only one telephone line. The call will be on February 3, 2003 from 2:00 p.m. to 3:30 p.m. EST. This conference can be accessed by calling 1-800-713-1971 [Federal call (404) 639-4100] and entering access code 996903.

The purpose of the telephone conference call is to help potential applicants:

- Understand the scope and intent of the Program Announcement for State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases;

- Understand the role of nutrition and physical activity population-based approaches, such as policy-level change and environmental support, in preventing and reducing obesity and other chronic diseases;

- Be familiar with the CDC funding policies and application and review procedures.

F.2. Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated based on the evaluation criteria listed, so it is important to follow them when writing the program plan. The narrative for this component, not including budget justification, should be no more than 30 double-spaced pages for Capacity Building program applications or 40 double-spaced pages for Basic Implementation program applications, printed on one side, with one-inch margins and 12-point font. Applicants may also submit appendices that include State nutrition and physical activity plan, resumes, job descriptions, organizational chart, facilities, and other supporting documentation not to exceed 100 total pages. Letters of support should include the specific roles and responsibilities of the collaborator/partner to the State plan or intervention. All materials must be suitable for photocopying (i.e., no audiovisual materials, posters, tapes, etc.).

1. Background and Recent History

Provide information on the background and recent history of your State health agency's capacity for the prevention and control of obesity and other chronic diseases through nutrition and physical activity. Describe how the State has built nutrition and physical activity capacity with CDC funds or other funding and complete the following table describing the current nutrition and physical staff,

including their education. Describe the kinds of staffing contract services/options if used to augment agency staffing.

Program	Dollar level and source	FTE for nutrition dedicated to the program, include credentials	FTE for physical activity dedicated to the program, include credentials	Type of staffing contract services/options used for nutrition or physical activity	Number of nutrition and physical activity graduate students
Nutrition/Physical Activity/Obesity (CDC funded)					
Nutrition/Physical Activity/Obesity (non-CDC funded, not including WIC), please specify					
Other:					
Other:					

Describe how the State has fulfilled the capacity building recipient activities to date, including developing a comprehensive State nutrition and physical activity plan to prevent obesity and other chronic diseases, descriptions of the development, implementation, and evaluation of nutrition and physical activity interventions relevant to obesity and other chronic diseases, prevention activities, and what programs and partners were involved. If applying as a basic implementation program, include an appendix responding to the evaluation questions in Attachment 10 located at

http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm.

2. Management Plan

a. Describe the management structure for the nutrition and physical activity program to prevent obesity and other chronic diseases. Describe plans with dates for hiring key staff. Include brief resumes of designated staff, the percentage of time they allocate to other health department programs, and job descriptions of existing and proposed staff.

b. Identify organizational placement of the program. Submit an organizational chart identifying relationships between programs such as cardiovascular disease, diabetes, cancer, health education and promotion. Identify clear and direct lines of authority, supervisory and fiscal controls, and the extent which the existing and proposed staff and organizational structure and systems demonstrate sufficient capacity and capability to efficiently and effectively conduct the proposed activities.

c. Identify staffing and contracting barriers for the State health agency in the last year. Describe how work plans addressing nutrition, physical activity or obesity changed or were delayed because of the

barriers. Also, identify strategies to carry out the proposed work plan considering current barriers. In particular, describe how the program will change if vacancies or hiring freezes occur.

3. Program Past Performance

Provide documentation to support your previous accomplishments that addressed the prevention and control of obesity and other chronic diseases through nutrition and physical activity. Include the following:

a. Evidence of State or community nutrition and physical activity policies, environmental supports, and/or legislative actions that are planned, initiated or modified for the prevention or control of obesity and other chronic diseases.

b. Evidence that communities have implemented a nutrition and physical activity plan for the prevention and control of obesity and other chronic diseases.

c. Evidence that an intervention for nutrition and physical activity was implemented and evaluated.

If applying for Basic Implementation funds, submit the State nutrition and physical activity plan for the prevention and control of obesity and other chronic diseases as well as any intervention protocols and outcomes in the appendix. Capacity Building applicants submit if available.

4. Burden (please limit to no more than three pages)

Provide information such as estimated prevalence of obesity and overweight and other chronic disease, its geographic and demographic distribution within the State using existing epidemiological data. Cite the source for and time period covered by these data. Describe high-risk populations, at a minimum by racial/ethnic, gender, age, and socioeconomic factors. If available, describe profiles of potential or already selected populations regarding their knowledge, attitudes, beliefs, health practices, and consumer patterns and habits relative to nutrition and physical activity aspects of obesity and other chronic diseases.

5. Program Work Plan - Provide a work plan that includes the following information:

a. Key Goal(s) and Objectives

Five-year project period impact objectives and one-year budget period process objectives that are specific, measurable, achievable, relevant, and time-framed to help achieve the goal(s) of the program as outlined in the "Recipient Activities" of this program component. If applying as a Basic Implementation program, attach the State's program logic model and evaluation plan. Capacity Building applicants submit if available.

b. Program Work Plan Methods

Provide a detailed description of the State's plan for conducting all program activities as outlined in the "Recipient Activities" of this program announcement, including methods for achieving each of

the proposed objectives, time-lines for all activities, responsible parties, and methods for monitoring progress. Describe the mechanism to regularly review, evaluate, and update the State plan to meet evolving needs.

Chronic disease prevention programs, by their nature, must be integrated and well coordinated due to common risk factors. Resources are scarce; it is essential that efforts not be duplicated. Explain how the State will avoid duplication (but enhance coordination and integration) with other CDC-funded programs that address nutrition and physical activity. Basic Implementation funded nutrition, physical activity, and obesity programs will be the primary location for the leadership and delivery of population-based health promotion rather than those responsibilities falling to CVD, Diabetes or other chronic disease specific programs. If a comprehensive State nutrition and physical activity plan already exists, describe how the process used to develop the plan included and integrated the activities of other chronic disease programs. Include the plan in the appendix.

6. Budget and Justification

Provide a detailed budget and line-item justification that is consistent with the stated objectives, purpose, and planned activities of the project. Distinguish budget lines that are related to planning activities versus those that are related to data collection and intervention activities. Applicants are asked to include budget items for travel for two trips, one trip to Atlanta, Georgia for three staff to attend a three-day training and technical assistance workshop and another trip for three staff to the annual national conference on chronic disease prevention and control. If in-kind contributions are being provided by the applicant, these should be documented.

G.2. Evaluation Criteria (100 points)

Each set of the evaluation criteria is scored using a 100-point system. Evaluation criteria 1 through 5 are applicable for both programs. Specific Program Work Plan criteria are provided for each funding level. Applications will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Program Work Plan (Total 50 points)

The extent to which the applicant addresses the items in Recipient Activities in E.2. and the Application Content in F.2. item 5.

Point distribution for Capacity Building programs goals, objectives, and work plan methods by recipient activities:

Develop a coordinated nutrition and physical activity program infrastructure. (10 points)

Conduct a planning process that leads to a comprehensive nutrition and physical activity plan to prevent and control obesity and other chronic diseases and start to implement the plan. (10 points)

Evaluate progress and impact of the State plan and intervention projects. (10 points)

Implement and evaluate an intervention to prevent obesity and other chronic diseases. (10 points)

Collaborate and coordinate with State and local government and private partners, including members of the population throughout the planning process. (5 points)

Identify and assess data sources to define and monitor the burden of obesity. (5 points)

2. Background and Recent History (15 points)

The extent to which the applicant addresses the items in Recipient Activities in E.2. and Application Content in F.2. item 1.

3. Management Plan (15 points)

The extent to which the applicant addresses the items in Recipient Activities in E.2. and the Application Content in F.2. item 2.

4. Program Past Performance (15 points)

The extent to which the applicant addresses the items in Recipient Activities in E.2. and the Application Content in F.2. item 3.

5. Burden (5 points)

The extent to which the applicant addresses the items in Recipient Activities in E.2. and the Application Content in F.2. item 4.

6. Point distribution for Basic Implementation programs goals, objectives, and work plan methods by recipient activities:

a. Develop a new or apply an existing intervention and evaluate it to prevent obesity and other chronic diseases. (10 points)

Implement the State comprehensive plan for nutrition and physical activity and review and update the plan periodically. Develop mini-grants and other mechanisms to support communities to adopt effective interventions. (10 points)

Evaluate progress and impact of the State plan and intervention projects. (10 points)

d. Identify, assess, or develop data sources to further define and monitor the burden of obesity. (6 points)

e. Expand the existing coordinated nutrition and physical activity program infrastructure. (5 points)

f. Expand partnerships with State Health Department units, the State Education Agency, other State agencies, local communities, and private partners to maximize impacts of the comprehensive program (3 points)

g. Collaborate with partners on secondary prevention strategies. (3 points)

h. Develop resources and training materials to help other State and local projects to adopt successful programs. (3 points)

6. Budget and Justification (Not weighted)

The extent to which the line item budget justification is reasonable and consistent with the purpose and program goal(s) and objectives of the cooperative agreement. (Both programs)

7. Human Subjects (Not Weighted)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Both programs)

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in any proposed research. This includes:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The proposed justification when representation is limited or absent.

c. A statement as to whether the design of the study is adequate to measure differences when warranted.

d. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community (ies) and recognition of mutual benefits.

Program Performance Measures

See Appendix C for the framework that will be used for measuring performance of the State Programs. Capacity Building Performance Measures for transitioning to basic implementation programs should include evidence that the applicant has significant capacity as specified in the Capacity Building Program Recipient Activities 1-6 and the program evaluation plan (See Attachment 10 located at http://www.cdc.gov/nccdphp/dnpa/rfainformation.htm) covering the following measurement areas:

Evidence of States conducting strategic planning activities to develop a comprehensive State nutrition and physical activity plan to prevent and control obesity and other chronic diseases.

Evidence that a quality comprehensive State nutrition and physical activity plan to prevent and control of obesity and other chronic diseases promotes coordination of activities across all relevant State and community programs in which relevant partners are identified in substantive roles.

Evidence of at least one community that implemented a nutrition and physical activity plan for the prevention and control of obesity and other chronic diseases.

Evidence of outcomes/impacts of at least one intervention evaluating nutrition and physical activity strategies to prevent or control obesity and other chronic diseases.

Evidence of State or community nutrition and physical activity policies, environmental supports, and/or legislative actions that were initiated, modified, or planned for the prevention or control of obesity and other chronic diseases.

Component 3 - Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN)

D.3. Availability of Funds

Approximately $9,200,000 is available to fund approximately 12 awards for grantees currently funded under program announcements 99135, 00115, and 01098. These grantees are only eligible for the second funding level (See Appendix A). To determine eligibility for first or second funding level see Appendices A and B which is found at the bottom of this document and at the CDC Web site address at http://www.cdc.gov/od/pgo/funding/grantmain.htm. Scroll down the Web page to "Chronic Disease Prevention/Health Promotion Heading." Click on Program Announcement Number 03022. The attachments will be located at the bottom of the program announcement. The project period is five years. The average award for Standard Demonstration Projects will be approximately $500,000. Projects that screen substantially more women than 2,500 per year and exceed the performance expectations may qualify for higher awards. Information on performance expectations are found in Appendix B which is found at the bottom of this document and at the CDC Web site address http://www.cdc.gov/od/pgo/funding/grantmain.htm. Scroll down the Web page to "Chronic Disease Prevention/Health Promotion Heading." Click on Program Announcement Number 03022. The attachments will be located at the bottom of the program announcement. The average award for Enhanced Projects will be approximately $1,000,000.

In addition, approximately $750,000 is available in FY 2003 to fund up to three WISEWOMAN Projects at the first funding level. Requests for these funds will be competitive. The project period is five years. In the first year, Standard Demonstration Project funding will range from $50,000 to $250,000. If all performance measures (see Appendix B) are completed at the first funding level, applicants may apply for the second funding level through their continuation applications.

Use of Funds

60/40 Requirements: Not less than 60 percent of cooperative agreement funds must be spent for screening, tracking, follow-up, lifestyle intervention, health education, and the provision of appropriate individually provided support services. Cooperative agreement funds supporting public education and outreach, professional education, quality assurance and improvement, surveillance and program evaluation, partnerships, and management may not exceed 40 percent of the approved budget [WISEWOMAN follows the same legislative requirements as the NBCCEDP, Section 1503 (a) (1) and (4) of the PHS Act, as amended; see

http://www.cdc.gov/wisewoman/legislationhighlight.htm

for more information on legislation]. Further information about the 60/40 distribution is provided in the WISEWOMAN Guidance Document: Interpretation of Legislative Language and Existing Documents. This can be accessed through the Internet at http://www.cdc.gov/wisewoman or by contacting the program technical assistant contact listed in Section "J. Where to Obtain Additional Information."

a. Inpatient Hospital Services: Cooperative agreement funds must not be spent to provide inpatient hospital or treatment services [Section 1504 g. of the PHS Act, as amended].

b. Administrative Expense:

Not more than 10 percent of the total funds awarded may be spent annually for administrative expenses. These administrative expenses are in lieu of and replace indirect costs [Section 1504 (f) of the PHS Act, as amended]. Administrative expenses comprise a portion of the 40 percent component of the budget.

c. Limit of Use of Funds for Case Management

Use of Federal funds for case management of women without alert values is strongly discouraged. This policy and the definition of alert values are found on the WISEWOMAN Web site Guidance Document at

http://www.cdc.gov/wisewoman.

Recipient Financial Participation - Matching Requirement

a. Recipient financial participation is required for this program in accordance with the authorizing legislation. Section 1502 (a) and (b) (1), (2), and (3) or the PHS Act, as amended, requires matching funds from non sources in an amount not less than one dollar for every three dollars of Federal funds awarded under this program. However, Title 48 of the U.S. Code 1469a (d) requires DHHS to waive matching fund requirements for Guam, U.S. Virgin Islands, American Samoa and the Commonwealth of the Northern Mariana Islands up to $200,000.

b. Matching funds may be cash, in-kind, or donated services, or equipment. Contributions may be made directly or through donations from public or private entities. Public Law 93-638 authorizes tribal organizations contracting under the authority of Title 1 to use funds received under the Indian Self-Determination Act as matching funds.

c. All costs used to satisfy the matching requirements must be documented by the applicant and will be subject to audit. Specific rules and regulations governing the matching fund requirement are included in the PHS Grants Policy Statement, Section 6. Matching funds are not subject to the 60/40 requirements described above under "Use of Funds." For further information about the matching fund requirement, see the WISEWOMAN Guidance Document.

Direct Assistance

No direct assistance funds will be awarded in lieu of financial assistance to successful WISEWOMAN component recipients.

E.3. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under "1. Recipient Activities," and CDC will be responsible for the activities listed under "2. CDC Activities."

Standard Project

Standard Demonstration Project (available for new applicants in FY 2003 and FY 2004, not available for new applicants in FY 2005 or later)

The major goal of a Standard Demonstration Project is to demonstrate the effectiveness of operational approaches to conducting the following activities for women aged 40-64 who participated in the NBCCEDP: Outreach, screenings for blood pressure, cholesterol, smoking, and other conditions (when appropriate); referral; lifestyle intervention (to include promotion of heart-healthy diet, increased physical activity, and tobacco cessation); tracking and follow-up; evaluation; professional and public education; and community engagement.

Enhanced Project

One major goal of an Enhanced Project is to use scientifically rigorous methods to test the effectiveness and cost-effectiveness of a behavioral or lifestyle intervention that is grounded in the social and cultural context of the target population and aimed at preventing cardiovascular disease. The other major goal is to translate and transfer successful interventions and program strategies to other programs that serve financially disadvantaged women. Some important resources for understanding the scope of these translation and transfer activities can be found at

http://www.replication.org/infores.html and http://www.replication.org/pdf/tool.pdf.

1. Recipient Activities for Standard Demonstration Projects and Enhanced Projects:

a. Develop a preventive health services program or a preventive health services research study/studies to include cardiovascular disease risk factor screening with mandatory cholesterol and blood pressure measurements built upon an extremely strong State, Territorial, or Tribal Breast and Cervical Cancer Early Detection Program with evidence provided of the strength of the BCCEDP Program.

b. Staff with at least two professional staff members to work full-time on WISEWOMAN (one of whom should be a full-time program coordinator and the other should have experience in nutrition, physical activity, or health education), or a plan for hiring such staff members. If staff must be hired, describe the staff that will manage the program until the hiring is completed. Describe the WISEWOMAN evaluation team and provide information on their experience and academic degrees.

c. Work with health care systems that can effectively deliver WISEWOMAN services and that target the population in need of these services. This can best be accomplished by working with a health care system in which the State, Territory, or Tribal BCCEDP has previously been effective and that has successfully engaged the community to provide additional services/support to the population in need.

d. Establish a cardiovascular disease prevention program as the primary focus, with culturally appropriate interventions addressing multiple risk factors that must include physical inactivity, poor nutrition (high intake of saturated fat and low intake of fruit and vegetables), and tobacco use. Other cardiovascular risk factors may be addressed such as overweight or obesity, and pre-diabetes or undiagnosed diabetes.

Recipients may develop other preventive services to be delivered, such as intervention services aimed at prevention or relief of the following: Osteoporosis, arthritis, influenza or other diseases for which vaccines are readily available, or other significant conditions/diseases which affect large numbers of older women.

e. States, Territories, and Tribal Agencies should implement screening, referral, and follow-up according to the recommendations of the National Cholesterol Education Program (NCEP) of the National Heart, Lung, and Blood Institute for cholesterol screening using the Adult Treatment Panel III (ATP-III) and the recommendations set forth for hypertension according to the 6th Joint National Report on the Detection, Evaluation and Treatment of High Blood Pressure published by the National Institutes of Health, National Heart, Lung, and Blood Institute. The guidelines can be obtained electronically at

http://www.nhlbi.nih.gov/guidelines/index.htm. National guidelines for addressing other risk factors can be found at http://www.cdc.gov/wisewoman.

Laboratories must be accredited under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet all applicable Federal and State quality assurance standards in the provision of any test performed. However, if a new, improved, or superior screening procedure becomes widely available and is recommended for use, this superior procedures will be utilized in the program. [Section 1503(b) of the PHS Act, as amended.]

f. Recipients should design culturally appropriate lifestyle interventions aimed at lowering blood pressure or cholesterol, improving physical activity or nutrition, or achieving smoking cessation in a similar target population. A New Leaf Choices for Health Living is an example of an intervention that has been effective in improving nutrition (see http://www.hpdp.unc.edu/wisewoman/newleaf.htm).

Alternatively, the intervention can be newly designed if it incorporates sound theoretical principles of behavioral change such as use of the socio-ecologic model to intervene at multiple levels, individual tailoring, self-efficacy, self-monitoring and reinforcement, readiness for change, small achievable steps, social support, collaborative goal setting, and strategies to overcome barriers (see monograph entitled Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program at http://www.hpdp.unc.edu/wisewoman/manual.htm. If applying as a Standard Best Practices project (available in FY 2005 and later), interventions should be designed following WISEWOMAN recommended best practices (available in FY 2005).

Recipients should propose methods aimed at sustaining behavioral change. Maintaining behavioral change should involve strategies to provide the participant with ongoing contact such as with health

facility staff or community health workers (either in person or by mail) and to educate regarding relapse prevention. The use of computer-tailored education can be especially useful (to view recommendations detailed in the monograph entitled Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience on the North Carolina WISEWOMAN Program see

http://www.hpdp.unc.edu/wisewoman/manual.htm.

Environmental supports aimed at sustaining behavioral change such as increased walking, healthier food choices, and smoking cessation should also be considered. These might include activities such as improving the safety of neighborhoods, advocating for walking groups at shopping malls, improving the quality of foods in local grocery stores and changing community norms around tobacco. Although WISEWOMAN applicants may not be able to completely fund these environmental strategies due to restrictions on the use of funds (see 60/40 Requirement in under "Use of Funds"), they may be able to establish strong partnerships with other CDC programs in their health department or agency that use community environmental and/or policy approaches (e.g., Nutrition/Physical Activity/Obesity, Tobacco Control, Diabetes, and Cardiovascular Health).

h. Recipients should propose methods aimed at sustaining the program in future years. Methods include using the principles of community engagement (for more information, see CDC's monograph entitled "Principles of Community Engagement" at

http://www.cdc.gov/phppo/pce/index.htm. Emphasis should be placed on developing traditional and non-traditional partnerships in the community through partnering with other CDC funded programs.

i. Plan or conduct evaluation strategies to include reporting of suggested minimum data elements and cost information (see WISEWOMAN Guidance Document at http://www.cdc.gov/wisewoman for a list of the suggested minimum data elements). Other evaluations are strongly encouraged and might include measures of program feasibility and acceptability, mapping neighborhood assets to determine resources before and after program implementation, increases in partnerships as a result of the program, improvements in medical care, the usefulness of community health workers in the program, increases in knowledge of providers, improvements in participant's self-efficacy, and so forth;

j. Formalize plans for Recipient Activities (a) to (i) through development of program protocols or conduct program operations according to previously developed and approved program protocols. Newly funded projects should conduct all program startup activities as detailed on page 18 of the monograph Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program at

http://www.cdc.gov/phppo/pce/index.htm and should be prepared to pilot test their methods.

Work collaboratively with other State, Territorial, or Tribal WISEWOMAN program staff and partners (such as CDC contractors) to develop methods that have the potential to be implemented in other WISEWOMAN programs.

2. CDC Activities:

a. Convene workshops, trainings, and/or teleconferences of the funded projects for sharing of information and solving problems of mutual concern.

b. Provide ongoing consultation and technical assistance to plan, implement, and evaluate program activities.

c. Conduct site visits to assess program progress and mutually resolve problems, as needed, and/or coordinate reverse site visits to CDC in Atlanta, GA.

d. Assist in the development of a research study protocol for IRB review by all cooperating institutions participating in the research project. If CDC IRB review is necessary, the CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed. For more detailed information on the CDC IRB see

http://www.cdc.gov/od/ads/hsr2.htm.

e. Collaborate with WISEWOMAN projects in the analysis of data and development of abstracts and publications that informs the program, public, scientific community, and Congress as to program progress and results.

f. Copy and distribute materials developed by State, Territorial, or Tribal WISEWOMAN projects for the purpose of aiding other WISEWOMAN projects and public health partners.

g. **Technical Assistance Phone Calls for WISEWOMAN Applicants**

WISEWOMAN staff have arranged for three technical assistance phone calls to answer questions related to the WISEWOMAN component of the CDC's recent program announcement for state funding, program announcement #03022, entitled "Chronic Disease Prevention and Health Promotion Programs." Information for each of the phone calls and who should participate is provided below.

New WISEWOMAN Applicants - Standard

WISEWOMAN will be hosting a call on February 4, 2003 for new WISEWOMAN applicants that are applying as standard projects. Conference Time: 03:00 PM Eastern

02:00 PM Central

01:00 PM Mountain

12:00 PM Pacific

- **Conference Duration: 02:00 Hours**
- **Conference Size: 20 Port(s)**
- **Bridge Telephone Number: 404-639-3277**

- **Conference Code: 138875**
- **Alternate Bridge Telephone Number: 800-311-3437**

New WISEWOMAN Applicants - Enhanced

WISEWOMAN will be hosting a call on February 5, 2003 for new WISEWOMAN applicants that are applying as <u>enhanced</u> projects.

- **Conference Time: 03:00 PM Eastern**
  02:00 PM Central

  01:00 PM Mountain

  12:00 PM Pacific
- **Conference Duration: 01:00 Hours**
- **Conference Size: 20 Port(s)**
- **Bridge Telephone Number: 404-639-3277**
- **Conference Code: 138875**
- **Alternate Bridge Telephone Number: 800-311-3437**

Current WISEWOMAN Projects

WISEWOMAN will be hosting a call on February 5, 2003 for current WISEWOMAN projects that are applying to continue their funding.

- **Conference Time: 04:00 PM Eastern**

  03:00 PM Central

  02:00 PM Mountain

  01:00 PM Pacific
- **Conference Duration: 01:00 Hours**

F.3. Content

Applications

The program announcement title and number must appear in the application. Use the information in the "Program Requirements, Other Requirements, and Evaluation Criteria" sections to develop the content. Your narrative should be no more than 30 double-spaced pages, printed on one side, with one-inch margins, and unreduced font.

WISEWOMAN Application Outline:

Please provide the following information and, as appropriate, a preliminary but realistic time-phased work plan that addresses all of the points below. Only existing WISEWOMAN projects are required to provide WISEWOMAN-specific information requested below. Applicants may apply for either the Standard Demonstration Project or the Enhanced Project, but not both.

1. Background and Need

Provide a brief description of the extent of the disease burden and the need among the priority populations and the background of the health care system to include:

a. The number of uninsured women living in the State/Territory/Tribal area by race/ethnicity by two age categories if possible, i.e. 40-49 years and 50-64 years.

b. The current health care system in which State, Territorial, or Tribal BCCEDP and WISEWOMAN sites operate (e.g. are the sites county health department clinics, community health centers, private providers, managed care organizations, etc.) and the appropriateness of the health care system for implementing effective interventions, adhering to program protocols, tracking difficult to reach women, and providing timely information on women who have high values of cholesterol and blood pressure.

c. Community involvement or engagement in the BCCEDP and/or WISEWOMAN project to include use of community health workers, use of community members, engagement in partnership activities with community agencies that serve financially disadvantaged women, use of referral systems to other community services, and so forth.

2. Infrastructure

Document the current State, Territorial, or Tribal BCCEDP and WISEWOMAN (if applicable) infrastructure including:

a. An organizational chart that shows the location of The WISEWOMAN Program in relationship to the agency's health promotion section, chronic disease section, minority, or women's health section, Breast and Cervical Cancer Early Detection Program, and to other programs that address chronic disease (e.g. cardiovascular health, tobacco, physical activity, nutrition, 5 A Day, diabetes, and obesity). Describe lines of communication between WISEWOMAN and the above-mentioned sections and programs.

b. The number of BCCEDP and WISEWOMAN sites in operation as of the January preceding the date of this application.

c. The total number of political subdivisions (e.g., counties) and the number of these subdivisions that had a BCCEDP site and the number that had a WISEWOMAN site as of January preceding the date of this application.

d. During the most recent program year include:

(1) The number of women served by BCCEDP and The WISEWOMAN Programs in the State, Territory, or Tribal area (provide data for each of the past 5 years, if available).

(2) The racial/ethnic characteristics of the population served (include educational Characteristics, if available).
(3) The percentage of women with a positive mammogram or pap test who did not go on for further diagnostics and reasons why women did not go on;
(4) The percentage of women with a WISEWOMAN alert value who did not go on for further diagnostics and reasons why women did not go on.
(5) The average length of time between a positive mammogram or Pap test and the receipt of a diagnostic test.
(6) The average length of time between detection of a WISEWOMAN alert value and the receipt of diagnostic test (see WISEWOMAN Guidance Document at http://www.cdc.gov/od/ads/hsr2.htm for the definition for alert values).

3. Program Planning for Upcoming Year
Describe how the program will decide or is currently conducting the following:
a. Site selection, the approximate number of sites to receive WISEWOMAN services, the characteristics of the sites, the proportion of State or Territorial BCCEDP sites that will receive WISEWOMAN services, and estimated number of women who are expected to receive such services during the upcoming year.
b. Screening and intervention services and start-up activities (if applying for Standard Demonstration Project funding level; see checklist of start-up activities in the WISEWOMAN Guidance Document at http://www.cdc.gov/wisewoman to be provided along with a time line for determining and implementing start-up activities, screening and intervention services [allowable screening and diagnostic procedures for the demonstration programs include resting pulse, blood pressure, serum total cholesterol, HDL-cholesterol, LDL-cholesterol, height and weight measurements, automated blood chemistry (to assess fasting blood glucose, potassium, calcium, creatinine, uric acid, triglyceride, or micronutrient levels), urine analysis (including urine cotinine), and paper and pencil tests, interviews, or computerized methods that measure level of physical activity, dietary intake, smoking, osteoporosis risk status, immunization status, or other chronic disease risk factors or preventable health problems. The use of program funds for other tests will require substantial justification by the program. The schedule of fees/charges should not exceed the maximum allowable charges established by the Medicare Program for the same or similar laboratory tests. (Fees/charges for services covered by Medicare may vary by location, thus, States or Territories should determine the appropriate reimbursement rates for their areas.)
c. A pilot study to test proposed methods.
d. Inclusion of letters of support for WISEWOMAN from a substantial number of State/Territorial BCCEDP site directors and medical staff.
e. Methods for tracking women through the system and after they leave the system [(for the purpose of bringing them back for further screening and intervention)(Standard Projects should ensure that at least 60 percent of new women receive the complete intervention)], for flagging, tracking, and managing women who need immediate referral because of extremely high blood pressure ($\geq$180 systolic blood pressure or 110 diastolic blood pressure), cholesterol (>400 mg/dL), or glucose levels (>375 mg/dL).
f. Program tracking to determine which women receive which interventions; routine reporting on the progress of the program (see suggested quarterly report format in WISEWOMAN Guidance Document at http://www.cdc.gov/wisewoman and reporting of minimum data elements. These minimum data elements will yield the performance measures that will determine whether a project

qualifies for additional funding. The complete set of performance measures are detailed in Appendix B.

4. Screening and Intervention
Document the ability of the program to screen and intervene upon women enrolled in the WISEWOMAN program including implementation of WISEWOMAN screening activities, the rationale and guidelines for implementing WISEWOMAN intervention activities, methods for reaching women from the State or Territorial BCCEDP for the purpose of WISEWOMAN screening and intervention and the use of outreach and community health workers to address barriers to program involvement, barriers to behavioral change, and barriers to maintaining contact for future health screenings and interventions.
5. Evaluation - (Standard Program):
a. Describe the current evaluation team or propose a plan to establish the evaluation team using criteria such as prior work experience, professional training, and academic degrees.
b. Describe the current evaluation plan or propose an evaluation plan that includes clearly stated evaluation objectives with a time line for the collection of data throughout the project.
c. Describe the current database or propose a database that details data elements, methods for data management, the creation of unique identifiers, methods for identifying women who need immediate treatment, and other important data procedures.

6. Evaluation - (Enhanced Program):
Submit an evaluation design to: 1) examine the impact of chronic disease risk factor intervention(s) on lowering blood pressure, improving cholesterol levels (lowering total cholesterol levels and raising HDL cholesterol levels), and improving other risk factors such as poor nutrition and inadequate physical activity at six and twelve months after intervention and program strategies. The plan for effectiveness should include:
a. The extent to which a university or Prevention Research Center will be involved in the evaluation design.
b. The preliminary evaluation questions to be answered.
c. The type of evaluation design (e.g. randomized controlled design) and rationale for using this type of design.
d. Length of follow-up and measurement intervals.
e. Protocol used to ensure that the maximum number of women will return for each evaluation.
f. Statistical techniques that will be used to analyze the data with preliminary estimates of the sample size needed to achieve adequate statistical power. To obtain the statistical power to evaluate the intervention, the program should add cholesterol and blood pressure screenings (and other optional screenings, if desired) to a sufficiently large number of State or Territorial BCCEDP sites to provide adequate statistical power for evaluating program effectiveness. States or Territories may want to consider including a total of at least 20 sites. The study design for this type of evaluation might include women from a number of sites assigned to intervention (i.e., the special intervention group) compared to women from a number of sites assigned to usual standard practice (i.e., the usual care group or comparison group). Other study designs may be proposed including randomizing women to each of arm of the study. A method of collecting information for the purpose of program evaluation should be developed and implemented. Voluntary reporting of Minimum Data Elements is recommended as part of the program evaluation. The plan for translation and transferring successful strategies should include:

(1) The extent to which the evaluation team includes staff with expertise in translation and transfer activities;
(2) Clear objectives regarding translating strategies into products using lay language, compiling information in clear, user-friendly format, testing of the translation package for usability;
(3) Methods for providing technical assistance, orientation and training on implementing and ensuring fidelity with regard to implementing the translation package;
(4) Methods for evaluating and refining the translation package and plans for dissemination of the final package;
A timeline with regard to translation and transfer activities. Some important resources for understanding the scope of these translation and transfer activities are found at http://www.replication.org/infores.html and http://www.replication.org/pdf/tool.pdf.

7. Collaborative Efforts
Provide a concise collaboration plan that addresses program methods and analyzing and publishing data with CDC and others. The following areas should be addressed:
a. Meeting and teleconferences attendance for the purpose of developing forms, tracking systems, measurements, policy, etc.
b. Analyzing data and co-authoring abstracts and publications; sharing information with CDC and its contractors (stripped of identifying information) on a twice-yearly basis.
c. Plans to collaborate with other health promotion experts in the health agency including nutritionists, physical activity experts, tobacco control experts, and others who promote a healthy lifestyle through better eating, weight management, physical activity, and smoking cessation.
d. For Enhanced projects, plans for developing a monograph and/or training on methods to help other projects adopt successful program practices (See example "Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program" at http://www.hpdp.unc.edu/wisewoman/manual.htm**.**

8. Budget and Justification:
Provide a detailed budget and line-item justification that is consistent with the stated objectives, purpose, and planned activities of the project. Applicants should note the following budget-related issues:
a. Budget for the following travel:
(1) Up to two persons to attend the Nutrition and Public Health Course that is sponsored by the University of North Carolina Prevention Research Center and the Centers for Disease Control and Prevention. This is a five-day course. For more information see http://www.hpdp.unc.edu/nph. Future topics and place to be determined. This is a mandatory training course that provides training with regard to WISEWOMAN Best Practices.
(2) Up to two persons to participate in the annual WISEWOMAN Project Directors Meeting that is held in conjunction with NCCDPHP Annual Chronic Disease Conference (four days) or other CDC Conferences. Details are provided at http://www.cdc.gov/nccdphp/conference/index.htm. This is a mandatory meeting for the purpose of sharing projects successes and challenges.
(3) One person to attend the Physical Activity and Public Health Course that is sponsored by the University of South Carolina Prevention Research Center and the Centers for Disease Control and Prevention. This is an eight-day Postgraduate Course on Research Directions and Strategies and a six-day Practitioner's Course on Community Interventions. See http://www.prevention.sph.sc.edu/seapines/index.htm. Or one person to participate in a non-CDC

sponsored professional meeting directly relevant to the program. (A tobacco cessation training course is highly recommended.)
(4) Cost Data and Minimum Data Elements:
Budget for collecting and reporting cost data and minimum data elements. (See WISEWOMAN Guidance Document at http://www.cdc.gov/wisewoman for list of minimum data elements.) Section 1505 [42 U.S.C. 300n-1] requires that applicants provide assurance that the grant funds be used in the most cost-effective manner.

G.3. Evaluation Criteria
Applications received from current grantees that are funded under program announcements 00115, 99135, and 01098 will be reviewed utilizing the Technical Review process. For applicants that apply competitively as Standard Demonstration Projects or Enhanced Projects, an independent objective review group appointed by CDC will evaluate each application individually using the following criteria:

1. Program Plan (35 points)
The extent to which the applicant has addressed Recipient Activities 1.a through 1.j and items 3.a through 3.g in the Application Content sections.

2. Screening and Intervention (Standard Projects: 25 points and Enhanced program: 15 points)
The extent to which the applicant has addressed Recipient Activities 1.b through 1.f and items 4 in the Application Content sections.

3. Evaluation Plan – (Standard Program: 15 points):
The extent to which the applicant has addressed Recipient Activities 1.h and items 5 in the Application Content section
Evaluation Plan – (Enhanced Program: 25 points):
The extent to which the applicant has addressed Recipient Activities 1.h and items 6 in the Application Content sections.

4. Background, Need, and Potential for Community Involvement (10 points)
The extension to which the applicant has addressed Recipient Activities 1.a and items 1.a through 1.c in the Application Content sections.

5. Infrastructure - (10 points)
The extent to which the applicant has addressed Recipient Activities 1.b and 1.d and items 2.a through 2.c in the Application Content sections

6. Collaborative Efforts (5 points)
The extent to which the applicant has addressed Recipient Activities 1.a and items 7 in the Application Content sections.

7. Human Subjects (not scored)
Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are

sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.
Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:
1.1 The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.
1.2 The proposed justification when representation is limited or absent.
1.3 A statement as to whether the design of the study is adequate to measure differences when warranted.
1.4 A statement as to whether the plans for recruitment and outreach for study participants includes the process recognition of mutual benefits.

Component 4: - State-Based Oral Disease Prevention Program

D.4. Availability of Funds

Approximately $2,600,000 is available in FY 2003 to fund approximately 13 Part 1 Capacity Building Program awards. It is expected that the Capacity Building Program average award will be $200,000, ranging from $65,000 to $400,000. Funding estimates may vary and are subject to change. No funding is available in FY 2003 for Part 2 Basic Implementation Program awards. Pending available funding resources, applications will be accepted in years two through five.

Use of Funds

Applicants may not use these funds to supplant oral health program funds from local, State, or Federal sources. Applicants must maintain current levels of support dedicated to oral health from other funding sources. Funding received under this program announcement cannot be used for the purchase of dental services, dental sealant equipment, or materials.

Recipient Financial Participation

Applicants requesting funding for community water fluoridation equipment will be required to provide matching funds. Matching funds are required from State and/or local sources in an amount of not less than one dollar for each four dollars of Federal funds awarded for community water fluoridation equipment under this program announcement. Matching funds are required from State and/or local sources in an amount of not less than one dollar for each four dollars of Federal funds awarded for a Basic Implementation Program.

Matching funds may be in cash or its equivalent, including donated or in-kind appropriate equipment, supplies, and or services. Do not include funds from other Federal sources including the Preventive Health and Health Services Block Grant.

CDC funding covers some of the costs of oral health core capacity, infrastructure, and community-based prevention interventions, but it is not intended to fully support all aspects of the oral health program.

Direct Assistance

You may request Federal personnel as direct assistance in years two through five, in lieu of a portion of financial assistance.

To request new direct-assistance assignees, include:

a. Number of assignees requested.

b. Description of the position and proposed duties

c. Ability or inability to hire locally with financial

Assistance.

d. Justification for request.

e. Organizational chart and name of intended supervisor

opportunities for training, education, and work

f. Opportunities for training, education, and work experience for assignees.

g. Description of assignee's access to computer equipment for communication with CDC (e.g., personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office).

E.4. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1.a and 1.b (Recipient Activities), and CDC will be responsible for the activities listed under 2.

CDC Activities.

1.a. Part 1 Capacity Building Program Recipient Activities and Performance Measures:

(1) Develop oral health program leadership capacity. Develop a State oral health team. Leadership capacity should include: (a) full-time dental director (oral health professional with public health training); (b) .25 time epidemiologic support at a minimum; (c) demonstrated access to at least .50 time of a water fluoridation engineer/specialist or coordinator, and (d) demonstrated access to appropriate program support, .50 to one time dental sealant coordinator, .25 time capacity for health education, health communication, and .25 time support staff, through leveraging of dollars, shared dedicated resources and letters of support.
Performance will be measured by evidence of established leadership capacity. Evidence of leadership capacity can be shown by: The composition of an oral health program team consistent with 1) above.
(2) Describe the oral disease burden, health disparities, and unmet needs in the State.
Describe the oral disease burden within the State and document unmet oral health needs of target populations and existing oral health assets (e.g., professional dental/dental hygiene schools, prevention interventions undertaken within the State).
Performance will be measured by evidence that State oral disease burden has been accurately described. Evidence can be shown by: a) a publicly available disease burden document describing oral disease burden and oral health disparities, issued in the past five years using the most recent data, preferably data no more than five years old; and b) document includes oral health status with indicators consistent with the National Oral Health System (NOHSS), the Water Fluoridation Reporting System (WFRS), and the ASTDD State Synopsis.
(3) Develop or update a comprehensive State Oral Health Plan.
Develop or update a comprehensive State Oral Health Plan for oral health promotion, disease prevention, and control that includes specific objectives for future reductions in oral disease and related risk factors and objectives for the promotion of oral health. The plan should provide specific, measurable, and time-phased objectives to accomplish each goal related to the logic model (see http://www.cdc.gov/OralHealth/index.htm for additional information). In addition, develop a comprehensive State Oral Health Plan (suggest five-year plan) that is available to the public, periodically updated, and developed in collaboration with the assistance of stakeholders. The Plan should address the following oral health areas: a) oral health infrastructure including current resources, gaps in resources and recommendations for their elimination; b) Healthy People 2010 objectives; c) caries; d) water fluoridation and school-based or school-linked sealant programs; e) description of priority populations and burden of disease; f) strategies to address oral health promotion across the lifespan, g) strategies to identify best practices that can be replicated; h) evaluation strategies and recommendations for monitoring the outcomes and impacts of plan implementation; i) implementation strategies, leveraging of resources, partnerships, and plan maintenance including roles and responsibilities of State and local agencies; and j) oral cancer, periodontal diseases, and infection control.
Performance will be measured by evidence that a comprehensive State Oral Health Plan has been completed. Evidence can be shown by development of a plan consistent with the process described and with elements (a) through (j) above.
(4) Establish and sustain a diverse Statewide oral health coalition. Establish a coalition to assist in the formulation of plans, guide project activities, and identify additional financial resources for this project. Coalition membership should be representative of stakeholder organizations within the State health department, within the State government and groups external to State government, for examples see
http://www.cdc.gov/OralHealth/index.htm.

Performance will be measured by evidence of a sustained, diverse statewide oral health coalition. Evidence can be shown by: a) extent of progress towards coalition sustainability, such as written by-laws, goals and objectives, plans and procedures for operation, past accomplishments, clerical staff support, and evidence of leveraging of resources; b) membership entities representing each, but not limited to, categories in the coalition framework at Web site; c) clear responsibility; d) coalition activity in infrastructure, community water fluoridation, and sealants. Coalition activities must address all of the following activities: Infrastructure development, community water fluoridation, school-based/school-linked dental sealant programs, unless the grantee can document how current activities in the State have already met or exceeded Health People 2010 objectives for these activities.

(5) Develop or enhance oral disease surveillance system. Develop key resources, data sources, and capabilities to promote the State's surveillance needs. See http://www.cdc.gov/OralHealth/index.htm for detailed outline of data sources to consider. Activities should include: a) establish plan for how data collection, analysis, and dissemination will support program activity, including a surveillance plan logic model consistent with the CDC Surveillance Logic model (see http://www.cdc.gov/OralHealth/index.htm); b) conduct surveillance so that key oral health indicators have been collected in a valid and timely manner using standard approaches with attention to comparability across States and consistent with annual data submission to the ASTDD's State Synopsis and data submissions to NOHSS, and updated at least every five years; and c) monitor water fluoridation on a monthly basis comparable and consistent with WFRS.

Performance will be measured by evidence of a developed or enhanced oral disease surveillance system. Evidence can be shown by: Documentation that key resources, data sources, capabilities and surveillance plan are in place to provide an adequate surveillance system via activities consistent with (a) through (c) above.

(6) Identify prevention opportunities for systemic, socio-political and/or policy change to improve oral health. Conduct a periodic assessment of policy and systems level strategies with potential to reduce oral diseases. The assessment should include identification of opportunities to make changes in policy and health systems to overcome barriers, capitalize on assets, increase capacity, and coordinate prevention interventions.

Performance will be measured by evidence of identification of socio-political and policy changes. Evidence can be shown by periodic assessments consistent with the activities above.

(7) Develop and coordinate partnerships to increase State-level and community capacity to address specific oral disease prevention interventions.

Identify, consult with and involve appropriate partners to assess areas critical to the development of State-level and community-based oral health promotion and disease prevention programs, avoid duplication of efforts, ensure synergy of resources, and enhance the overall leadership within the State. Partnerships should augment the oral health coalition.

Performance will be measured by evidence of the development and coordination of partnerships. Evidence can be shown by: a) collaborative partnerships with Statewide and local entities (e.g., Memorandum of Understanding (MOU) with other State agencies, joint dedication of resources); b) broad range of partnerships inside and outside of the State Health Department, encouraging the focus on prevention interventions.

(8) Coordinate and implement limited community water fluoridation program management.

Provide coordination and management of a fluoridation program, provide/develop fluoridation training materials for engineers and water plant operators, and evaluate community water fluoridation accomplishments and new and/or replacement water fluoridation equipment.

Performance will be measured by the development, implementation, and coordination of a water fluoridation program. Evidence can be shown by: a) extent the water fluoridation program incorporates and makes progress towards the 1995 Engineering and Administrative Recommendations for Water Fluoridation (EARWF), including: 1) daily testing; 2) access to .50 fluoridation engineer; 3) targeted inspection activity; 4) basic fluoridation training; b) monthly monitoring consistent with the Water Fluoridation Reporting System (WFRS); c) percent of fluoridated water systems consistently maintaining optimal levels of fluoride as defined by State and consistent with EARWF; d) document communities and populations receiving new or replacement fluoridation equipment.

(9) Evaluate, document, and share State program accomplishments, best practices, lessons learned, and use of evaluation results.

Evaluation activities should: a) be consistent with the CDC oral health global logic model, work plan: (see http://www.cdc.gov/OralHealth/index.htm) the CDC Evaluation Framework for Evaluating Public Health Programs (http://www.cdc.gov/mmwr), the CDC Guide to Evaluating Surveillance Systems (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm, and consider assessments of changes in oral health outcomes, as well as process evaluations consistent with the Association of State and Territorial Dental Directors' Best Practices evaluation criteria (see http://www.cdc.gov/OralHealth/index.htm); b) document outcome evaluation measures including but not limited to percentage of population receiving fluoridated water and dental sealants; c) include evaluation efforts consistent with indicators developed for "supported States evaluation plan" (see http://www.cdc.gov/OralHealth/index.htm); d) be used to improve recipient activities above; and (e) be institutionalized as an on-going activity. Sharing of State program accomplishments, best practices, and lessons learned may include participation in forums for exchanging ideas and identification of methods and avenue for dissemination such as the CDC Chronic Disease Conference, and the National Oral Health Conference as well as local and State supported forums (e.g., State Summits, State dental and dental hygiene association meetings).

Performance will be measured by evidence that evaluation has been completed, State evaluation capacity and activities have become institutionalized; State program accomplishments have been collected, evaluated, and shared with stakeholders; and evaluation results are used to improve program performance. Evidence can be shown by: 1) documentation of evaluation activities consistent with (a) through (e) above; and 2) documentation of participation in scientific forums consistent with the activities above.

(10) Capacity Building Prevention Intervention (To be undertaken after Part 1 Capacity Building Program 1-9 from above have been met)

a. Develop and Implement a water fluoridation program. Provide or develop fluoridation educational materials, as appropriate, to promote water fluoridation. Implement a program to support new replacement water fluoridation equipment. Evaluate the accomplishments of the water fluoridation program.

Performance will be measured by the development, implementation, and coordination of a water fluoridation program. Evidence can be shown by: 1) documentation of appropriate education and promotion efforts; 2) documentation of communities and populations receiving replacement fluoridation equipment by funding source; 4) extent of progress towards reaching or exceeding Health People 2010 objective of 75 percent of population on public water supplies receiving fluoridated water.

b. Develop, coordinate and implement limited school-based or school-linked dental sealant programs. Describe and document the number of eligible public elementary or secondary schools, and existing related oral health assets. Document infrastructure is in place for the coordination and management of school-based or school-linked dental sealant program and show collaborative working relationships and formal agreements (e.g., MOA, MOU, or other written agreement between the State Health Department and the State educational agency).
Develop school-based or school-linked dental sealant programs targeting public elementary or secondary schools located in: a) urban areas, and in which more than 50 percent of the student population of that school or school entity is participating in Federal or State free and reduced meal programs; or b) rural school districts having a median income that is at or below 235 percent of the poverty line, as defined in section 673 (2) of the Community Services Block Grant Act [42 U.S.C. 9902(2)].
Performance will be measured by the development, implementation, and coordination of school-based/school-linked dental sealant programs. Evidence can be shown by: 1) extent that priority populations have been identified; 2) extent that implementation strategies appropriate to State setting have been developed; percent and number of children in funded programs receiving at least one permanent molar sealant; proportion of eligible schools participating in program; and proportion of children participating in free and reduced cost lunch program receiving at least one sealant.
Optional Cost Analysis Recipient Activities and Performance Measures:
Measures include the collection, tracking, and completion of cost analysis for school-based/school-linked dental sealant program. Evaluate the accomplishments, efficiency, and effectiveness of the implemented school-based/school-linked dental sealant programs. Proposals may include requests for technical assistance for the following optional performance measures:
Performance will be measured by the collection, tracking, and accomplishment of a cost-analysis for school-based or school-linked dental sealant programs. Evidence can be shown by: a) documentation of baseline mean pit and fissure caries severity (i.e., pit and fissure DMFS) in targeted permanent molars among children three years older than target population; b) cost-analysis report published and submission made to the ASTDD Best Practices Project.
1.b. Part 2 BASIC IMPLEMENTATION Program Recipient Activities and Performance Measures:
Basic Implementation Recipient Activities and Performance Measures include evidence that applicant continues to meet CAPACITY BUILDING program and CAPACITY BUILDING-PREVENTION INTERVENTION program activities and performance measures in section 1.a. above.
(1) Develop a Statewide community water fluoridation program or maintain Statewide fluoridation program that has reached the Healthy People 2010 objective. Enhance or expand existing community water fluoridation demonstration or pilot project into a statewide program showing annual progress.
Performance will be measured by evidence that water fluoridation efforts result in significant progress towards meeting, maintaining or exceeding Healthy People 2010 goals. Evidence can be shown by: a) extent that Statewide water fluoridation program incorporates and makes progress in meeting the Engineering and Administrative Recommendations for Water Fluoridation (EARWF, 1995), including: 1) monthly monitoring and participation; 2) additional fluoridation engineers and/or specialist if appropriate; 3) all fluoridation engineers and/or specialists attend CDC fluoridation engineers and/or specialists attend CDC fluoridation training or equivalent; 4) all water plant operators receive basic fluoridation training; 5) all adjusted fluoridated water systems have annual inspections to insure that all the technical recommendations, including the a) safety requirements of EARWF are followed; b) all split sampling reference labs should participate in the

CDC Lab Proficiency Testing Program; c) document progress in increasing percent of fluoridated water systems consistently maintaining optimal levels of fluoride as defined by State and consistent with recommendations outlined in EARWF; d) document progress toward reaching or exceeding Healthy People 2010 objective; e) document communities and populations receiving new or replacement fluoridation equipment.

(2) Develop Statewide school-based or school-linked dental sealant program or maintain school-based or school-linked dental sealant program if the Healthy People 2010 objective has been met. Enhance or expand existing school-based or school-linked dental sealant demonstration or pilot project into a Statewide program showing annual progress. School eligibility criteria as stated in (10) (b) above will be used.

Performance will be measured by evidence that grantee is implementing and expanding school-based or school-linked dental sealant programs Statewide. Evidence can be shown by: a) documentation of progress towards reaching or exceeding goal of school-based or school-linked sealant programs in at least 50 percent of eligible schools; b) significant progress towards increasing: the percent and number of children in Statewide funded programs receiving at least one permanent molar sealant; proportion of eligible schools participating in program; and proportion of eligible schools participating in program; and proportion of children in funded programs participating in free and reduced cost lunch program receiving at least one sealant; c) demonstrated participation in ASTDD Best Practices project; d) demonstrated leadership capacity in dissemination and technical assistance to other State sealant programs; e) progress towards sustainability and institutionalization of sealant program through leveraging of dollars, partnership participation, billing Medicaid and/or SCHIP or other sources of support.

(3) Develop other evidence-based, population-based, intervention strategies consistent with the State Oral Health Plan. Strategies should include policy and systems level approaches. Interventions should be population based, with objectives that specify the population wide changes sought and may address use of dental sealants, water fluoridation efforts, tobacco use, diabetes, poor nutrition, oral health education and, secondary prevention.

Performance will be measured by demonstration of implementation of evidence-based, population-based strategies. Evidence will be shown by: a) documentation of evidence-based for intervention initiative; b) extent that population-based interventions meet the established objectives specifying the population-wide changes sought; and c) submission to the ASTDD Best Practices Project.

(4) Evaluate intervention components.

Design and implement a public health practice evaluation system that collects and analyzes information to be used to measure program progress, community capacity changes, short-term and distal outcomes. Evaluation results and related findings should be used to add to and/or enhance program implementation.

Performance will be measured by evidence that State evaluation capacity and activities have become an on-going normative activity and that State program accomplishments have been collected, evaluated and shared with stakeholders. Evidence can be shown by: a) demonstration that the recipient is taking a leadership role in providing technical assistance and transfer of practice knowledge to other States; and b) quantification (in terms of dollars) of resources used and returns on those resources.

(5) Expand oral health program leadership capacity. Expand State oral health team beyond CAPACITY BUILDING level. Provide National leadership by sharing results, with one another, best practices, and other lessons learned to help shape the national agenda and improving the oral health of the public. Capacity should include: a) epidemiologic support .50 time at a minimum; b)

demonstrated access to 1.0 time fluoridation engineer/specialist or coordinator (may be less for States with small number of water systems or more for States with a large number of water systems); c) demonstrated access to appropriate program support at a minimum: 1.0 time program coordinator, 1.0 time dental sealant coordinator, .50 time capacity for health education, .50 time health communication, .50 time data manager, .25 time grant writer, 1.0 time support staff, and regional consultants, through leveraging of dollars, shared dedicated resources, and letters of support.
Performance will be measured by evidence of expanded leadership and access to needed functions through personnel, leveraging of dollars, shared dedicated resources and/or letters of support, sharing through publications and presentations at national and regional meetings. Evidence can be shown by: a) the minimum composition of the oral health program is consistent with the activities outlined above; b) demonstrated with the activities outlined above; c) demonstrated evidence of sharing best practices and other lessons learned inside and outside of the State borders through publications and meeting presentations.
(6) Develop and maintain expanded surveillance capacity. The surveillance system is maintained and sustainable, and able to compare State or smaller area data to those from national data sources. Surveillance system should be able to conduct original analyses or forge good working relationships with in-State agencies that will conduct the original analyses. Refer to surveillance logic model at Web site for more information.
Activities should include: a) development of regional or county level indicators; b) development of surveillance system quality checks, establishment of data cleaning protocol, and document data linkages and security procedures; c) utilization of original analytic analyses and comparisons to national data in dissemination activities and reports; d) documentation of regional or county level indicators; and e) collaboration with other programs in the health department to answer key epidemiological questions of mutual interest, e.g., diabetes, tobacco, cancer, MCH.
Performance will be measured by evidence that surveillance is on-going, sustainable activity within the State, is expanded beyond the basic requirements of a core system, and uses data to direct program planning and oral health promotion. Evidence can be shown by: Documentation of activities (a) through (e) above.
(7) Expand the diverse statewide oral health coalition. Expand statewide oral health coalition and address institutionalization and sustainability.
Performance will be measured by evidence of a sustained, diverse statewide oral health coalition with established plans for membership and recruitment of diverse stakeholders. Evidence can be shown by: a) extent that coalition has been significantly expanded in both numbers and types of members and documentation of expanded coalition activities; b) documentation of dedicated support staff; c) documentation of established communication measures and outreach to community, policy makers and stakeholders; d) extent of progress towards coalition sustainability such as meeting minutes, schedule of meeting dates and locations; and e) documentation of active support from stakeholders including funding sources and in-kind contributions.
(8) Address program sustainability by broadening resources. Address the institutionalization of the oral health unit, oral health surveillance system, statewide coalition, and the State's best practice programs.
Performance will be measured by demonstration of condition supportive of the sustainability of State oral health infrastructure and programs. Evidence can be shown by measures including non-award funding and measures that activities are institutionalized; b) demonstration of environment conducive to the growth of promotion of oral health in three major support areas: Infrastructure and processes, resources and culture/context in the State, and local health department(s); c)

demonstration of shared dedicated resources, leveraging of dollars, and supportive partnerships; d) demonstrated legislative and other State government support.
(9) Collect, track and complete cost analysis for school-based or school-linked dental sealant program.
Evaluate the accomplishments, efficiency, and effectiveness of the implemented school-based or school-linked dental sealant programs.
Performance will be measured by the completion of a cost-analysis for school-based or school-linked dental sealant programs. Evidence can be shown by: a) documentation of baseline mean pit and fissure caries severity (i.e., pit and fissure DMFS) in targeted permanent molars among children three years older than target population; and b) cost-analysis report published and submission made to the ASTDD Best Practices Project.
2. CDC Activities
a. Update and provide information related to the purposes and/or objectives of the program announcement related to recipient activities.
b. Provide programmatic and technical assistance for recipients and their stakeholders and partners through programmatic and technical consultation, workshops, information exchanges and other forms of guidance, assistance and information sharing to assist the recipient in: a) the assessment of oral health status and behaviors of target sub-populations; b) the design and implementation of strategies for prevention interventions based on best available scientific evidence; c) the design, evaluation and monitoring of interventions effectiveness; d) the distribution of information documenting lessons learned, best practices and program costs; and (e) the evaluation of State oral health programs.
c. Communicate and share information, evaluations, data, and programmatic activities with other recipients and partners, as appropriate.
d. Coordinate conference calls, workshops, and other information sharing opportunities, as appropriate.
F.4. Content
The program announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.
This section will outline the requirements for each program and will note additional requirements for each specific Part.
The narrative for Part 1 CAPACITY BUILDING Program should be no more than 36 pages, double-spaced, printed on one side, with one-inch margins, and 12-point Universal unreduced font.
(Part 1) CAPACITY BUILDING Program
1. Executive Summary (not to exceed two pages)
Provide a clear, concise two-page written summary to include: a) synthesis of need for oral health programs; b) changes in infrastructure required to support proposed programs; c) major proposed objectives for implementation of Work Plan (see section (4) below and http://www.cdc.gov/OralHealth/index.htm); d) amount of Federal funding requested under Part 1 of this cooperative agreement.
2. Statement of Need (not to exceed seven pages) a) describe oral disease burden within the State, indicate specific sub-populations and source(s) of data provided; b) describe current assets and capacity of the State to reduce identified burdens. Current grantees under Program Announcement 01046, should not include CDC funding from Program Announcement 01046 under existing

resources; c) identify barriers and facilitators likely to affect the reduction of oral disease burden; and d) describe gaps in Statewide infrastructure affecting the capability of the applicant to perform recipient activities and operate prevention programs.
3. Five-year Plan (Goals) (not to exceed five pages)
a. Design a logic model for State oral health program. See Web site for the CDC Logic Model Template. Incorporate planned Capacity Building Prevention Interventions if appropriate, into State oral health logic model; b) Goals: List feasible, realistic goals related to logic model to achieve in five years.
4. One-year Plan, Activities and Timeline (not to exceed nine pages)
Objectives: Provide specific, measurable, and time-phased objectives to accomplish each goal related to the logic model and the performance measures outlined in Section E above. State how achievement of objectives will contribute to meeting the goal; b) describe the one-year work plan for achieving each objective in Section (3) above. See Web site for the CDC Work Plan Template, c) the one-year work plan should describe activities planned to complete each objective. Applicants must link each time-phased objective and performance measure from Section E above, with the activities intended to support that objective; d) one-year work plan should establish a time line for completion of each component or major activity; e) identify specific individual (person) responsible for each objective or activity in the one-year work plan.
5. Evaluation Plan (not to exceed seven pages)
a. Describe plan for monitoring progress toward achieving objectives stated in Section (4) above; b. for each objective, specify how achievement will be documented including measures, data collection protocols, and data quality required to obtain needed information; c. using the logic model as a framework, specify: 1) indicators for process and outcome objectives; 2) expected increase in capacity of the State oral health program, delivery systems, and communities; 3) changes in oral health outcomes; d) plans for analysis, interpretation and reporting of findings; e) plans for use of findings; and f) provide a time-line for the completion of the evaluation.
6. Program Management (not to exceed six pages)
a) Describe employing agencies or institutions, as well as professional backgrounds of existing or proposed staff who will be responsible for each functional project aspect, including in-kind staff resources and percent of time commitment (including in-kind staff resources and percent of time commitment (Include Curriculum Vitae as appropriate); b) provide evidence of State support for proposed project; c) describe coalitions involvement in planning, implementation, and evaluation; d) describe management, coordination team and responsibility for different program aspects; e) identify staff that will direct evaluation efforts including additional team members assigned to evaluation tasks. Provide a detailed description of expertise, experience, and delineation of staff, and responsibilities for program evaluation.
7. Budget and Accompanying Justification (no page limitation)
Submit a detailed budget and line item justification that is consistent with the purpose of the program and the proposed project objectives and activities, using the format of the sample budget provided at http://www.cdc.gov/OralHealth/index.htm.
To the extent necessary, applicants are encouraged to include travel for: a) up to four persons associated with this project to each annually attend up to two technical assistance workshops. For the purpose of the initial funding period, budget for the workshops, training courses, and technical assistance meetings to be held in Atlanta, Georgia; and b) two staff to annually participate in the National Oral Health Conference. For the purpose of the initial funding period, applicant should budget for the 2004 National Oral Health Conference.

The narrative for Part 2 BASIC IMPLEMENTATION Program should be no more than 45 pages, double-spaced, printed on one side, with one-inch margins, and 12 point Universal unreduced font.
(Part 2) BASIC IMPLEMENTATION Program
Use the application guidance from Part 1 Capacity Building Program with the exception of the page limits and the additional section as outlined below.
1. Executive Summary (not to exceed four pages)
2. Statement of Need (not to exceed seven pages)
3. Eligibility (not to exceed seven pages)
a) Outline how State oral health program has accomplished activities and performance measures under the Capacity Building Program; b) outline how your demonstration/pilot CAPACITY BUILDING PREVENTION INTERVENTIONS have been successful. Include a description of activities and performance measures under Section E.1.a as appropriate.
4. Five-year plan (Goals) (not to exceed five pages)
5. One-year Plan, Activities and Timeline (not to exceed nine pages)
6. Evaluation Plan (not to exceed seven pages)
7. Program management (not to exceed six pages)
8. Budget and Accompanying Justification (no page limit)

G.4. Evaluation Criteria

Applicants received from current grantees that are funded under Program Announcement 01046, will be reviewed utilizing the Technical Review process. Applications received from unfunded applicants (new), will be evaluated individually against the following criteria by an independent review group appointed by CDC.
Applications received from grantees funded under Program Announcement 01046 will be reviewed by independent reviewers utilizing the Technical Acceptability Review (TAR) process.
CAPACITY BUILDING Program Criteria
a. One Year Plan (30 points)
The extent to which the applicant has addressed Recipient Activities 3 and item 4.a in the Application Content section of Component 4.
b. Five Year Plan (20 points)
The extent to which the applicant has addressed Recipient Activities 3 and item 3 in the Application Content section of Component 4.
c. Program Management (20 points)
The extent to which the applicant has addressed Recipient Activities 1, 7, 8, and 10 and item 6 in the Application Content section of Component 4.
d. Statement of Need (15 points)
The extent to which the applicant has addressed Recipient Activities 1 and 2 and item 2 in the Application Content section of Component 4.
e. Evaluation Plan (15 points)
The extent to which the applicant has addressed Recipient Activities 5, 6, and 9 and item 5 in the Application Content section of Component 4.
f. Budget (not scored)
The extent to which the applicant has addressed item 7 in the Application Content section of Component 4.
BASIC IMPLEMENTATION Program Criteria
a. One Year Plan (30 points)

The extent to which the applicant has addressed Recipient Activities 3 and item 4.a in the Application Content section of Component 4.
b. Five Year Plan (20 points)
The extent to which the applicant has addressed Recipient Activities 3 and item 3 in the Application Content section of Component 4.
c. Evaluation Plan (20 points)
The extent to which the applicant has addressed Recipient Activities 5, 6, and 9 and item 5 in the Application Content section of Component 4.
d. Program Management (20 points)
The extent to which the applicant has addressed Recipient Activities 1, 7, 8, and 10 and item 6 in the Application Content section of Component 4.
e. Statement of Need (10 points)
The extent to which the applicant has addressed Recipient Activities 1 and 2 and item 2 in the Application Content section of Component 4.
f. Budget (not scored)
The extent to which the applicant has addressed item 7 in the Application Content section of Component 4.

Component 5 - Arthritis
D.5. Availability of Funds
Approximately $6,000,000 is available in FY 2003 to fund up to 36 awards. Approximately $3,640,000 is available to fund 28 existing Capacity Building Program Level A grantees under Program Announcement 01097. Capacity Building Program Level A grantees will undergo a technical review of their application and will be funded pending receipt and approval of a technically acceptable application. It is expected that the average award will be $135,000 ranging from $120,000 to $150,000.
Approximately $2,360,000 is available to fund six to eight Capacity Building Program Level B programs. Requests for these funds will be competitive and will be reviewed by an independent objective review panel. It is expected that the average award will be $275,000 ranging from $250,000 to $300,000.
Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds. The interim progress report will be used as evidence of Capacity Building Program Level A attainment of their respective goals and objectives and readiness to compete for the next level of funding should funds be available. Capacity Building Program Level A grantees wishing to compete for the next level of funding should submit an application that is responsive to the Capacity Level B Program Performance Measures, Application Content and Recipient Activities section of this program announcement including a line-item budget and budget justification. Applications for advancement from a Level A to Level B program will be reviewed by CDC staff utilizing the Technical Acceptability Review (TAR) process. Applications can be submitted in fiscal year 2004, 2005, or 2006. Funding decisions will be made on the basis of satisfactory progress on the appropriate Performance Measures as evidence by required reports and the availability of funds. Capacity Building Program Level A programs that unsuccessfully compete for Capacity Building Program Level B funding will be funded for a Capacity Building Program Level A.
Use of Funds

Cooperative Agreement Funds may not be used to supplant State or Local funds. In addition, funds may not be used to support primary prevention activities.

Recipient Financial Participation

Matching funds are not required for this program.

E.5. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1a. (Recipient Activities for Capacity Building Program Level A) and 1b. (Recipient Activities for Capacity Building Program Level B Programs) and CDC will be responsible for the activities listed under 2. CDC Activities.

1a. Recipient Activities for Capacity Building Program Level A

Staffing: Establish a full-time arthritis program manager to oversee arthritis program activities and to promote an arthritis program within the State. All arthritis program managers are strongly encouraged to take the training "The Arthritis Challenge" and "Arthritis: The Public Health Approach" located at http://www.astdhpphe.org.

Performance will be measured by the extent to which the program is appropriately staffed in a timely manner as evidenced by the submission of the name of the program manager, the date of hire, and their completion of the training, "Arthritis: The Public Health Approach" as documented by a course completion certificate.

2. Partnerships: Establish an advisory group or coalition to guide, review, and provide direction for the State in all activities directed at reducing the burden of arthritis. The advisory group, at a minimum, should include the local chapter(s) of the Arthritis Foundation. In addition, the State should consider the following as members of the advisory board or coalition:

a. Individuals with expertise in arthritis;

b. Agencies/organizations with activities relevant to arthritis, resources for arthritis activities, and access to target populations (e.g., Area Agencies on Aging, Medicaid/Medicare, managed care organizations, American Association of Retired Persons, senior centers, and faith communities); and

c. Persons with arthritis or family members of persons with arthritis.

As appropriate, States should establish internal workgroups with other components of State government that are directly or indirectly involved in some aspect of arthritis control and prevention.

Performance will be measured by the extent to which there is evidence of diverse, active, and viable partnerships. Documentation should include minutes of meetings, lists of members, copies of by-laws or written operating procedures.

3. Surveillance:

a. Define and monitor the prevalence and impact of arthritis using the Behavioral Risk Factor Surveillance System (BRFSS). It is recommended that funded States collect data using the Arthritis Optional Module of the BRFSS in odd years (i.e., 2003, 2005, 2007)

b. Issue a State of Arthritis Report using, at a minimum, 2001 BRFSS arthritis data. (Arthritis data was collected by all States in calendar year 2001 through the BRFSS). This activity should be completed within the first two years of the cooperative agreement.

c. For years two and beyond surveillance activities should be expanded to include the measuring of intervention reach and effects. Measuring reach includes, but is not limited to, establishing mechanisms to determine annual availability and delivery of evidenced-based self-management programs such as ASHC, PACE, and Arthritis Foundation Aquatics programs. Availability measures the number of programs offered and their geographic dispersion; delivery measures both the number of programs given and the number of persons with arthritis attending. Measuring effects includes,

but is not limited to, measuring changes in health impacts, improvement in quality of life, or functioning among those attending the above programs.
Performance will be measured by:
a. The extent to which there is evidence that the burden of arthritis has been defined using BRFSS data that identifies demographics, prevalence, and related risk behaviors (i.e., physical activity and obesity). A State of Arthritis Report has been published and disseminated.
b. The extent to which the grantee is able to demonstrate the ability to define and monitor the number of evidenced-based self management courses available within the State and the number of individuals impacted by these programs.
4. State Plan: Develop or update a State Plan for Arthritis that outlines a proposed framework for activities to reduce the burden of arthritis. This document should be planned with partners and include activities to be implemented by the partners. The plan should not address health department activities only and should be completed within the first eighteen months of the cooperative agreement.
Performance will be measured by the extent to which documentation is provided that a written State plan for arthritis is completed. The plan should contain a description of the State burden of arthritis, and assessment of resources and resource gaps, strategies to decrease the burden of arthritis, priorities, and time-line for implementation of interventions. The plan should be endorsed and supported by partner organizations.
5. Interventions: Implement one or more strategies from the State Arthritis Plan that is consistent with the Public Health Framework for Arthritis (see http://www.cdc.gov/nccdphp/arthritis) with a focus on the immediate effects and/or short term goals as outlined in this framework. Activities should be data driven. Applicant should develop implementation plans and evaluation strategies for the proposed intervention(s). Activities should be implemented with a focus on one or more of the following areas:
a. Evidence-based Self Management Education and Physical Activity Interventions: Broaden the reach of evidence-based self management programs, e.g., the Arthritis Self Help Course (ASHC), the promotion of physical activity in individuals with arthritis using land-based exercise programs such as People with Arthritis Can Exercise (PACE) or water-based such as the Arthritis Foundation Aquatics Program.
b. Health Communications Campaigns: Develop or utilizing health communications interventions that will increase/enhance knowledge and beliefs necessary for appropriate management of arthritis. Communications strategies should be designed to increase self-management beliefs and behaviors and to increase the belief that self-management is an important part of arthritis management. The communications activity can be targeted to people with arthritis, and their families, the general public, or non-physician health professionals. CDC developed health communication campaign Physical Activity. "The Arthritis Pain Reliever," may be used. A summary of this material will be posted at http://www.cdc.gov/nccdphp/arthritis. Physician education efforts, while worthy, will not be considered as part of this activity.
Performance will be measured by the extent that the grantee can provide documentation that one or more evidenced-base intervention was implemented including: the process used for selecting the intervention, the target audience, the location of the intervention, and data used to support the decision to implement.
1b. Recipient Activities for Capacity Level B Programs
In addition to continuing and enhancing the Recipient Activities for Capacity Building Program Level A, Capacity Building Program Level B Program will include:

1. Surveillance: Examine the availability and applicability of other State-based data sources including but not limited to data from outpatient/ambulatory care settings, managed care organizations, and follow back surveys of BRFSS respondents. Pharmacy data may also prove useful to better define the burden of arthritis within the State. All surveillance activities outside of BRFSS should be directly linked to programmatic activities.
Performance will be measured by the extent to which non-BRFSS data have been examined and have informed program decisions or enhanced existing activities.
2. Interventions: Implement two or more strategies from the State Arthritis Plan that is consistent with the Public Health Framework for Arthritis with a focus on Evidenced-Based Arthritis Education Programs and/or Health Communications. Capacity Building Level B programs may choose to implement and evaluate physical activity or self-management interventions other than ASHC, aquatics and PACE, that may be beneficial and effective in reducing arthritis related pain and disability and improving the quality of life among persons with arthritis. For these interventions, States must propose an implementation and evaluation plan. This plan should include a description of the program, expected program outcomes, implementation strategies, the role of partners and consultants in implementing and evaluating the program, and the evaluation plan. The evaluation should describe how impact will be measured, domains of interest, proposed data collection tools, and how data will be collected and analyzed. A time-line should be included.
Performance will be measured by:
a. The extent to which grantee can provide documentation that two or more evidenced-base interventions were implemented including: the process used for selecting the intervention, the target audience, the location of the intervention, the role of partners, and data used to support the decision to implement.
b. The extent to which non-evidence based programs have been implemented and evaluated.
Notes:
All funded States are expected to adhere to the most current surveillance, intervention, and health communication recommendations that will be posted at www.cdc.gov/nccdphp/arthritis/index.htm.
2. CDC Activities
Provide consultation and technical assistance to plan, implement, and evaluate each component of the program.
Provide current information on the status of National efforts as they relate to the implementation of recipient activities.
d. As needed, provide technical assistance in the coordination of surveillance efforts and the use of other data systems to measure and characterize the burden of arthritis, provide standard analyses of BRFSS data for States, and provide data for national level comparisons.
Facilitate communication among arthritis programs,
other government agencies, and others involved in arthritis control and prevention efforts.

F.5. Content

The program announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. Applications for Capacity Building Program Level A should be no more than 30 pages and Capacity Building Program Level B Programs no more than 40 pages excluding Federal forms, budget, justification, abstract, and appendixes. All applications should be double-spaced, printed on one side, with one-inch margins, and 12-point font. All applicants should also submit as appendices, resumes, job descriptions, organizational charts, and

any other supporting documentation as appropriate. All graphics, maps, overlays, etc., should be in black and white and meet the above criteria. All submitted materials must be suitable for photocopying. Your application must be submitted UNSTAPLED and UNBOUND.

1. Abstract (All applicants)

A one-page, single-spaced, typed abstract must be submitted with the applicants. The heading should include the title of the program, organization, name and address of the project director, telephone number, facsimile number, and e-mail address. The abstract should clearly state which level of activities the applicant is applying for: Capacity Building Program Level A, or Capacity Building Level B Program. The abstract should briefly list major program elements and activities. A table of contents that provides page numbers for each section should follow the abstract.

2. Background/Current Status

Capacity Building Program Level A Programs:

Describe the burden of arthritis in the State. Identify what data sources are being used, the barriers the State currently faces in developing and implementing a program for arthritis, and identify the specific needs and resources available for arthritis activities.

Capacity Building Level B Programs:

a. Applicants for Capacity Building Programs Level B should provide evidence that they have significantly met the requirements specified in the Recipient Activities for Capacity Building Programs Level A (see Program Recipient Activities Section).

b. In addition, the applicant should adequately describe the burden of arthritis within the State including how the program defines arthritis using BRFSS and other data.

c. Include a description of the barriers the State currently faces in further developing and implementing programs for the control of arthritis.

3. Work-Plan

Provide a work plan that includes objective, methods, evaluation plans, and a time-line for each for the required elements cited in Recipient Activities above. Objectives should describe what is to happen, by when, by whom, and to what degree. Methods should describe the plan for achieving each of the objectives including a description of how partners will be involved. Also included should be a description of how progress toward attainment of the objectives will be monitored.

a. Staffing (All Applicants)

Describe how proposed or existing staff has the relevant background, qualifications, and experience to manage a public health program. Include a description of their role in promoting an arthritis program within the State, their specific responsibilities, their role in coordinating activities between relevant programs within the State, how the organizational structure will support the staff's ability to conduct proposed activities, and the level of effort and time to be devoted to the arthritis program. Job descriptions, resumes if available, and an organizational chart should be included.

b. Partnerships (All Applicants)

Include plans for developing partnerships with the local chapter(s) of the Arthritis Foundation, State and local agencies, Federal agencies, and others with an interest in arthritis. If partnerships have already been developed, the applicant should describe the process used, and the role of advisory groups, partnerships, or coalitions in the development and implementation of activities in the State Plan for Arthritis. Partnerships are expected to have been ongoing and viable. Applicants should include copies of agendas for all partnership meetings within the past two calendar years. Letters of support should be submitted and should describe the nature and extent of involvement by outside partners.

c. Surveillance

Capacity Building Program Level B:

1. Describe plans to monitor the burden of arthritis within the State using BRFSS data and include plans for the development and dissemination of a State of Arthritis Report.
2. Applicant should also describe the method to be used to develop mechanisms to measure programmatic reach and effects of evidenced-based arthritis self-management programs as defined in the "Recipient Activities" section of this announcement.
3. In addition to criteria under Capacity Building Program Level A, applicants for Capacity Building Level B Programs should present plans to examine the availability and applicability of other State-based data sources as described in the "Recipient Activities" section.

d. State Plan

Capacity Building Program Level A:

Applicants should describe the process to be used for engaging relevant partners and developing a State arthritis plan. If a State plan has been developed, describe the process used for its development, provide agendas for planning meetings, and provide the executive summary of the State plan.

e. Interventions

1. Applicants should describe the process to be used to select the intervention to be implemented.
2. If an already existing state plan or partnership has provided guidance for the selection of the intervention, describe the relationship between the intervention and strategies identified within the State plan and the Public Health Framework for Arthritis. Provide a description of implementation plans, the proposed intervention(s) activity(ies), the target population, geographic location, the actual methods of implementation, a time-line, evaluation strategy, and the role of partners in this process.

Capacity Building Program Level B:

1. Address the elements 1 and 2 under Capacity Building Program Level A

2. If proposing the implementation of non evidenced-based intervention(s), provide an implementation plan that includes a description of the program and expected outcomes. In addition, the evaluation plan should describe how impact will be measured, domains of interest, proposed data collection tools, and how data will be analyzed.

f. Evaluation (All Applicants)

Applicant should provide a plan that is capable of monitoring progress toward meeting specified project objectives.

g. Budget (All Applicants)

Provide a detailed line-item budget and justifications consistent with the purpose and proposed objectives. Budgets should include travel for one to two program staff to attend a two-day meeting in Atlanta. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection. If indirect costs are requested, a copy of the Indirect Cost Rate Agreement should be included.

G.5. Evaluation Criteria (100 Points)

Applications received from current grantees that are funded under Program announcement 01097, will be reviewed utilizing the Technical Review process. Applications received from States funded under program announcement 99074 and all other applicants will be evaluated individually against the following criteria by an independent review group appointed by CDC.

A. Capacity Building Program Level A (100 points)

1. Need/Current Status
Capacity Building Program Level A (15 points) Capacity Level B (25 points)
The extent to which the applicant addresses the requirements identified in Section F.5. (Application Content) item 3. Point distribution is listed below.
2. Staffing
Capacity Building Program Level A (20 points) Capacity Building Program Level B (10 points)
The extent to which the applicant addresses the
requirements identified in section E5 (Recipient
Activities) section 1a. item 1 and section F.5
(Application Content) item 3a.
3. Partnerships
Capacity Building Program Level A (15 points) Capacity Building Program Level B (15 points)
The extent to which the applicant addresses the requirements identified in Section E.5 (Recipient Activities) section 1a. item 2 and section F.5 (Application Content) item 3b.
4. Surveillance
Capacity Building Program Level A (15 points) Capacity Building Program Level B (20 points)
The extent to which the applicant addresses the
requirements identified in Section E.5 (Recipient Activities) section 1a. item 3; section 1b item 1 and section F.5 (Application content) item 3c.
5. State Plan
Capacity Building Program Level A (15 points) Capacity Building Program Level B (0 points)
The extent to which the applicant addresses the requirements identified in Section E.5 "Recipient Activities" section 1a. item 4 and section F.5 (Application Content) item 3d.
6. Interventions
Capacity Building Program Level A (15 points) Capacity Building Program Level B (25 points)
The extent to which the applicant addresses the requirements identified in Section E.5 "Recipient Activities" section 1a. item 5; section 1b item 2 and section F.5 "Application Content" item 3e.
7. Evaluation
Capacity Building Program Level A (5 points) Capacity Building Program Level B (5 points)
The extent to which the applicant addresses the requirements identified in Section F.5 (Application content) item 3f.
8. Budget (not scored)
The extent to which the applicant addresses the requirements identified in Section F.5 (Application content) item 3g.
9. Human Subjects (not scored)
Does the application adequately address the requirements of title 45 CFR Part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Component 6 - Behavior Risk Factor Surveillance Systems (BRFSS)

D.6. Availability of Funds

Approximately $5,000,000 is available in FY 2003 to fund approximately 54 existing grantee under program announcement 99044. It is expected that the average award will be $75,000, ranging from $50,000 to $100,000. It is expected that the awards will begin on or about June 30, 2003 and will be

made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Use of Funds

Funds provided under this program announcement cannot be used to conduct community-based pilot or demonstration projects. Cooperative agreement funds may not be used to supplant State or local funds. Cooperative agreement funds may not be used to provide patient care, personal health services, medications, patient rehabilitation, or other cost associated with treatment. Funds awarded under this program announcement may be obligated and expended only for those BRFSS surveillance, data collection, and related activities identified in the Notice of Grant Award.

E.6. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities

a. At a minimum, identify a program director and BRFSS data coordinator dedicated to overall coordination and operations of BRFSS.

b. Adopt the standard BRFSS written protocol that has been developed and formulate a plan for developing and conducting BRFSS data collection activities in conformance with protocols used by other participating States and delineated in the "BRFSS User's Guide" and numbered memorandums (The "BRFSS User's Guide" is available at http://www.cdc.gov/brfss).

c. Develop and implement plans and written procedures for ongoing analysis of behavioral risk factor data Statewide and for selected local areas.

d. Develop and implement plans and written procedures to ensure the routine use of BRFSS data for directing program planning, evaluating programs, establishing program priorities, developing specific interventions and policies, assessing trends, and targeting relevant population groups.

e. Develop and implement plans for the use of BRFSS data to address emerging Public Health chronic disease and injury issues within the State.

f. Develop and implement procedures to increase collaboration with and among State, local, and, as appropriate, national, public, private, voluntary, for-profit and nonprofit agencies, organizations, and universities that analyze data or seek to reduce chronic disease and injury morbidity and mortality.

g. Assure active cooperation and collaboration with recipients of funding form other CDC supported programs (cancer, tobacco use, diabetes, alcohol use, women's health, etc.) and identify opportunities to link program and BRFSS efforts where appropriate and reinforcing, including co-funding of BRFSS activities.

h. Ensure adequate and, as required, periodic training of State BRFSS interviewers. Interviewers must follow the standard BRFSS questionnaire script developed in collaboration with BRFSS member States and should be trained with appropriate standards for telephone interviewing. (The BRFSS Interviewer Training is located in the training section of the BRFSS Web site referenced above in 1.b.)

i. Develop, maintain, and make available to CDC monthly, electronic BRFSS data sets for data management (i.e., editing, cleaning, and weighting).

j. Conduct monthly, monitoring data quality and data management (i.e., through verification and validation efforts).

k. Develop and implement an analysis plan.

l. Participate with others in individual and multi-State analyses comparing data across BRFSS States.

m. Disseminate BRFSS findings through presentations and publications to health departments, professional societies, voluntary agencies, universities, other BRFSS States, and other interested individuals and organizations.
n. Make data and BRFSS findings available for training workshops and meetings at least once a year (i.e., BRFSS Conference).
o. Assure that CDC receives final end-of-year BRFSS data sets on or before February 15 of the following year.
2. CDC Activities
a. Assist BRFSS member States to develop an annual survey instrument to be used by States with States and CDC programs.
b. Assist BRFSS member States to establish standard survey protocols to be followed by States and disseminate them in the "BRFSS User's Guide" and in numbered memorandums; and, as appropriate, assist in the development of State-specific protocols.
c. Assist BRFSS member States with designing and obtaining appropriate telephone samples.
d. Assist BRFSS member States in the development of data processing procedures to be used by States and CDC to produce edited data files with standard, uniform formats. Provide program software, training, and on-going technical assistance for operations management, questionnaire data entry, and development of the BRFSS analysis database.
e. Develop and provide to States semi-annual and annual summary reports on selected risk factors related to the leading causes of State morbidity and mortality in a standardized and uniform manner.
f. Assist in training State staff related to data collection, data analysis, interpretation, and use.
g. Conduct or assist with the specification of cleaning, weighting, data editing, variable and format layouts of all data files.
h. Provide technical assistance to resolve problems regarding data collection procedures, response rates, sampling procedures (unbiased sampling and estimate omissions), and database file completeness.
i. Collaborate with State, Federal, and other programs on joint analysis of BRFSS data.
j. Coordinate and facilitate the interchange of technical information among cooperative agreement recipients.
k. Provide BRFSS States with programmatic, epidemiological, and statistical technical assistance.
l. In collaboration with State(s) conduct multi-State and single-State analyses and facilitate dissemination and translation of findings.
m. Participate with States in workshops, training, and meeting to exchange information.
n. Conduct site visits to monitor program operations and to provide technical assistance as needed.
Performance will be measured based on accomplishment of the activities listed above. Evidence can be demonstrated through the quality of data, adherence to survey recommendations, utilization of BRFSS data for program planning and evaluation.

F.6. Content

The program announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated on the criteria listed, so it is important to follow them in laying out program plans. The narrative should be no more than 30 double-spaced pages, printed on one side, with one-inch margins, and unreduced font.
Available funds will be allocated first for the costs of an estimated base of 2,000 completed 100-question surveys in each State.
1. Program Management

a. Identify the percentage of the project coordinator's time and related costs for project activities and describe procedures or process (i.e., contractors or in-house) for the management of data collection. Provide job descriptions, resumes, and organizational charts.
b. Include written procedures or describe plans to develop and implement the following:
c. BRFSS data analysis Statewide and for local areas.
d. Use of BRFSS data for directing program planning, program evaluation, setting program priorities, developing interventions, assessing trends, and targeting relevant population groups.
e. To address emerging public health issues.
f. To increase collaboration among State, local, and other agencies, organizations, and universities that analyze data or seek to reduce chronic disease and injury morbidity and mortality.
g. Provide a list of training taken by key BRFSS staff, to include data collection/interviewer staff, within the previous 12 months. Training list should include course title, a brief description of course content, dates of training, and names and titles of staff attending the training.
h. Provide a copy of projected staff training with the course title, course description, dates of training, and names and titles of staff who will be attending training.
2. Operational Plan
a. Provide an estimate of the number of interviews to be completed in addition to the base number of 2000 completed interviews per State per year.
b. Provide a list of the survey questions to be asked in addition to the base-length questionnaire.
c. Identify the percentage of an analyst's time and related costs for analyzing data collected.
d. Provide the title and author(s) of publications produced and/or distributed using BRFSS data.
e. Upgrading computer-assisted telephone interviewing systems and computer systems for analysis and Internet activities.
f. Describe the nature and extent of collaboration and coordination with and support (i.e., financial, shared resources, etc.) from other State programs.
3. Evaluation
Describe the procedures currently used or planned to monitor the performance of the data collection system, adherence to prescribed data collection protocols, and the extent of the use and dissemination of the data.
4. Budget
Provide a detailed budget and line-item justification for all operating expenses. The budget should be consistent with the State's objectives and planned activities of the project. Budget requests should include the cost of two two-day trips to Atlanta for two individuals and the cost of one five-day trip (including travel days) for up to two individuals to attend the annual BRFSS conference. The budget should address funds requested, as well as the applicant's in-kind or direct support.

G.6. Evaluation Criteria (100 points)

Applications received from current grantee that are funded under program announcement 99044, will be reviewed utilizing the Technical Review process.
1. Operational Plan (50 points)
The extent to which the applicant has addressed Recipient Activities 1.b, 1.c, 1.d, 1.e, 1.k, 1.m, and items 1 through 6 in the Application Content section.
2. Program Management (25 points)
The extent to which the applicant has addressed Recipient Activities 1.a, 1.g, 1.h, 1.i, and items 1 through 5 in the Application Content section.
3. Evaluation (25 points)

The extent to which the applicant has addressed Recipient Activities 1.i, 1.j, and 1.o, and item 3 in the Application Content section.
4. Budget (Not Weighted)
The extent to which the applicant has addressed item 4 in the Application Content section.

Component 7 - Genomics and Chronic Disease Prevention
D.7. Availability of Funds
Approximately $1,000,000 is available in FY 2003 to fund approximately three to five States program awards. It is expected that the average award will be $200,000 ranging from $150,000 to $250,000.
Use of Funds
Funds awarded under this component may not be used to conduct genomic research or pay for patient services such as genetic testing or counseling. Cooperative agreement funds may be used to develop or enhance the State Health Department's capacity for planning with other agency programs and outside partners, and implementing the use of genomic information (e.g. genetic testing and family history data) in public health policy and programs. Funds may also be used to enhance data collection through disease registries and other surveillance systems and to develop public health work-force competency in the use of genomics for disease prevention. Developing genomic leadership capacity will enhance comprehensive chronic disease prevention and health promotion by establishing cross-cutting activities with one or more disease-specific programs and increasing collaboration across the agency in epidemiology, environmental health, infectious disease, maternal and child health, and related programs that increase the effectiveness of chronic disease prevention.
E.7. Program Requirements
In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities.
1. Recipient Activities
Note: In this announcement, integrating genomic and the use of family history into chronic disease program planning, policy development, and intervention design includes, but is not limited to, a) establishing or expanding leadership capacity in the field of genomics, b) developing and implementing population-based assessments and incorporating genomic information into disease-specific data collection through surveillance and registries, c) developing expanded uses of genomics in programmatic activities including BRFSS and the analysis of vital records and other sources important in population-based analysis, d) educating the health workforce, policy makers, and the public about the importance of understanding the role of family history and genetic risk factors in disease etiology and prevention, and e) specifically preparing the chronic disease workforce for using genomic tools to reduce the burden of specific diseases and understanding the benefits and limitations of available genetic tests.
a. Develop or strengthen the health agency organizational capacities for assessing and utilizing existing genomics and public health program experience and expertise in planning the integration of genomics into existing chronic disease prevention and health promotion programs.
b. Acquire or enhance the leadership capacity required to integrate genomics into existing or planned chronic disease prevention and health promotion programs. In this effort, coordination of the core public specialties (such as epidemiology, laboratory services, policy development, and infectious disease prevention) to integrate genomics and family history, as appropriate, is required. The use of genomics within public health requires collaboration with academic and health care organizations

that can provide technical assistance and expertise in expanding program and policy development. Leadership capacity may include: (a) designating a State agency-wide, or chronic disease genomics coordinator or team, expanding existing leadership roles to include chronic disease and other disease-specific responsibilities, and/or coordinating a team representing all or selected public health disease programs; (b) the availability of adequate epidemiologic, genomics, laboratory, health education, communications expertise and program support; and (c) a mechanism for assessing and increasing the genomic and public health competency of the chronic disease work-force through technical assistance and specific training activities. Information of work force competency is available at:
http://www.cdc.gov/genomics/training/competencies/comps.htm.
c. Utilizes national, regional and State training and technical assistance resources for program development, and expands collaborative relationships with key academic institutions such as the Centers for Genomics and Public Health (Link to:
http://www.cdc.gov/genomics/training/competencies/comps.htm.
Ensures that State professional organizations, industry, community representatives or key partners and community are key partners throughout the planning process.
d. Develop and implement a plan for integrating genomics and related risk assessment tools such as family history into core public health activities and priorities for one or more chronic infectious, environmental, Maternal and Child Health or other public health programs during the first year.
e. Plan and coordinate the assessment and use of various types of targeted risk assessment strategies related to enhanced disease prevention based on genomics and family history tools. Collaborate with professional, industrial, and academic resources and partners in the testing, assessment, and usage of risk assessment tools that help organize knowledge about inheritable factors into a process for early recognition of increased disease susceptibility and strategies for disease prevention.
f. Plan and coordinate the assessment and use of various types of targeted risk assessment strategies related to enhanced disease prevention based on genomics and family history tools. Collaborate with CDC and the Centers for Genomics and Public Health in the testing, assessment, and usage of family history tools that help organize knowledge about heritable factors into a process for early recognition of increase disease susceptibility and strategies for disease prevention.
2. CDC Activities
a. Convene workshop and/or teleconference of recipient Programs for information-sharing and problem solving.
b. Provide ongoing guidance, consultation, and technical assistance to plan, implement, and evaluate all aspects of program activities. Activities include assisting with analyses and interpretation of the rapidly expanding knowledge base on public health genomics and findings from qualitative and quantitative research; guiding program evaluation, and sharing community, environmental and policy strategies to promote the integration of genomics across health agency programs associated with chronic disease program activities. Disseminate relevant state-of-the-art research findings and public health recommendations related to genomics and disease-specific prevention and control.
c. On a consultative basis, assist in the development and review of intervention protocols and program evaluation methods.
d. Coordinate national level partnerships with relevant organizations and agencies involved in the translation of genomics and family history into relevant guidelines and recommendations for public health policy development and program action.

F.7. Content

The program announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. Applications should be no more than 20 pages excluding Federal forms, budget, justifications, abstract, and appendixes. All applications should be double spaced, printed on one side, with one-inch margins, and 12-point font. All applicants should also submit as appendices, resumes, job descriptions, organizational charts, and any other supporting documentation as appropriate. All graphics maps, overlays, etc., should be in black and white and meet the above criteria. All submitted materials must be suitable for photocopying. Your application must be submitted UNSTAPLED and UNBOUND.

1. Abstract

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the program, organization, name and address of the project director, telephone number, facsimile number, and e-mail address. The abstract should briefly list major program elements and activities. A table of contents that provides page numbers for each section should follow the abstract.

2. Background, Need, and Understanding

Describe the status of health agency activities and capacity for establishing coordinated leadership in genomics to guide crosscutting health policy and program development. Provide status and level of involvement of chronic disease, infectious disease, environmental health, epidemiology, maternal and child health, and laboratory within this agency leadership capacity. Describe the extent to which genomics is integrated into chronic disease programs function and the proposed or actual placement of a focus for genomic activities within that structure. Discuss any agency actions implemented or planned that facilitate the integration of genomics and/or the use of family history in developing risk factor assessments and targeting disease prevention efforts. Provide evidence of the readiness of the agency and it's program to integrate genomics and family history into chronic disease prevention and health promotion planning, policy development, and intervention activities. Identify the specific components of this, or other chronic disease program announcements, or the crosscutting issues, to be addressed.

3. Work-plan

Provide a work plan that addresses each of the required elements cited in the Recipient Activities above. The work plan should include:

a. Program Objectives for each of the Recipient Activities. Objectives should describe what is to happen, by when, by whom, and to what degree.

b. The proposed method of achieving each of the objectives.

c. The proposed plan for evaluating progress toward attainment of the objectives.

d. A milestone, time line, and completion chart for all objectives for the project period.

4. Budget

Provide a detailed line-item budget with justifications consistent with the purpose and proposed objectives. Clearly differentiate budget amounts and activities requested through this component from the resources or activities of other components or programs. Budgets should include travel for one to two persons to attend a two-day meeting in Atlanta. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection. If indirect costs are requested, a copy of the Indirect Cost Rate Agreement should be included.

G.7. Evaluation Criteria

Applications for this component will be objectively reviewed against the following criteria by an independent review group appointed by CDC.

1. Background, Need, and Understanding (25 points)

The extent to which the applicant describes Background, Need as presented in the application content section (F.8.4.), and demonstrates an Understanding of the intent and focus of the program as presented in the Recipient Requirements (E.8.1).

2. Work Plan

a. Program Objectives (25 points)

The extent to which the applicant presents specific, measurable, and time phased objectives for each Recipient Requirement (E.8.1..a-e).

b. Methods of Achieving the Objectives (25 points)

The extent to which the applicant's plan for each Recipient Requirement (E.8.1 a-e) will accurately monitor, and permit re-direction of activities.

c. Plan for Evaluating Progress (15 points)

The extent to which the evaluation plan for each Recipient Requirement (E.8.1 a-e) will accurately monitor, and permit re-direction of activities.

d. Milestone, Timeline, and Completion Chart (10 points).

The extent to which the chart(s) provided represents an effective tool for monitoring program progress.

3. Abstract (Not scored)

The extent to which an overview of the program is provided in a clear and concise manner.

4. Budget and Justification (Not scored)

The extent to which the line item budget justification is reasonable and consistent with purpose of this component and program goal(s) and objectives of the cooperative agreement.

Program Performance Measures

Performance measures for the first year:

1. Evidence that States have performed a review of organizational and operational capacities for integrating genomics into public health practices and policies.
2. Evidence that States have identified and defined the nature and scope of population-based data, genomics information, and leadership capacity necessary to integrate genomics into chronic disease and other public health program activities.
3. Evidence that States have developed and initiated a plan for integrating genomics and risk assessment tools such as family history into one or more chronic, infectious, environmental, maternal and child health, or other public health programs.
4. Evidence that the States have formed partnerships with academic institutions, professional organizations, community and industry groups and involved them in the planning of genomic integration activities

Five year performance measures:

1. Evidence that the States have integrated genomics and related risk assessment tools, such as family history, as a routine component of disease investigations and analysis.
2. Evidence that the States have used population-based data and the expanding genomics knowledge base to develop or revise chronic, environmental, and infectious disease programmatic activities, interventions, and policies.
3. Evidence that the States have conducted preliminary evaluations of the impact of genomics in case identification, disease prevention, economic, and disease specific health outcome.

Note: This section applies to all components.

H. Submission and Deadline

Submit the original and two copies of CDC form 0.1246.
Forms are available in the application kit and at the following Internet address:
http://www.cdc.gov/od/pgo/forminfo.htm
Note: Your application should be submitted as one application but should consist of specific Categorical Components to allow each categorical program to remove their section of the application to assist with the preparation of the application. The application must be received by 4:00 p.m. Eastern Time March 28, 2003. Submit the application to:

Technical Information Management Section- Program Announcement 03022
Procurement and Grants Office
Center For Disease Control and Prevention
2920 Brandywine Road, Room 3000
Atlanta, Georgia 30341-4146

Deadline Applications will be considered as meeting the deadline if they are received before 4:00 p.m. Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to 1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or if significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline. Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

I. Other Requirements

Technical Reporting Requirements
Provide CDC with original plus two copies of
1. Interim progress report, the interim progress report will be due February 15, 2004, and subsequent interim progress reports will be due on the 15th of February each year through February 15, 2008, except for Component 6. The second report (annual progress report) is due 90 days after the end of the budget period (30th of September). The progress report, due in February, will serve as your non-competing continuation application and must include the following elements:
a. A succinct description the program accomplishments/narrative and progress made in meeting each Current Budget Period Activities Objectives during the first six months of the budget period (June 30th through December 31st).
b. A succinct description of the program accomplishments/narrative and progress made in meeting each Current Budget Period Activities Objectives during the first six months of the budget period (June 30th through December 31st).
c. The reason(s) for not meeting established program objectives and strategies to be implemented to achieve unmet objectives.
d. Current Budget Period Financial Progress.
e. New Budget Period Proposed Activities and Objectives.
f. Detailed Line-Item Budget and Justification.
g. For all proposed contracts, provide the name of contractor, method of selection, period of performance, scope of work, and itemized budget and budget justification. If the information is not

available, please indicate "To Be Determined" until the information becomes available; it should be submitted to CDC Procurement and Grants Management Office contact identified in this program announcement.
Applicable for Program Components 2 (Nutrition, Physical Activity and Obesity), 3 (WISEWOMAN), 4 (State-Based Oral Disease Prevention), and 5 (Arthritis), only:
The interim progress report that is due on the 15th of February will also be used as evidence of a program's readiness to move from level to the next higher level based on attainment of goals and objectives when funding is available. Applicants wishing to compete for the next funding level should submit items a, b, d, e, f, and g above and the information requested in the next funding level Recipient Activities and Application Content identified in this program announcement including a line item budget and budget justification.
Applicants can be submitted in fiscal years 2004, 2005, 2006, and 2006 but be received by February 15th of the specific submission year. Funding decisions will be made on the basis of attainment of current goals and objectives as evidenced by the require reports, application score, and the availability of funds.

2. Financial status report, no more than 90 days after the end of the budget period. The financial status report should include an attachment that identifies unspent balances for each program component.

3. Final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following **additional requirements** are applicable to this program.
AR-1 Human Subjects Requirements (Component 2 & 3)
AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research (Component 2 & 3)
AR-7 Executive Order 12372 Review
AR-8 Public Health System Reporting Requirements
AR-9 Paperwork Reduction Act Requirements
AR-10 Smoke Free Workplace Requirements
AR-11 Health People 2010
AR-12 Lobbying Restrictions

J. Where to Obtain Additional Information
For this and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address
http://www.cdc.gov
Click on "Funding" then "Grants and Cooperative Agreements."

Business management and technical assistance may be obtained from:
Lucy Picciolo, Grants Management Specialist
Procurement and Grants Office
Centers for Disease Control and Prevention
2920 Brandywine Road, Room 3000

Atlanta, GA 30341-4146
Telephone number: 770-488-2683
E-mail address: lip6@cdc.gov

Business management technical assistance for the U.S. Territories may be obtained from:
Charlotte Flitcraft, Contract Specialist
Procurement and Grants Office
Centers for Disease Control and Prevention
2920 Brandywine Road, Room 3000
Atlanta, GA 30341-4146
Telephone number: 770-488-2632
E-mail address: caf5@cdc.gov

Business Management technical assistance for Territories may be obtained from:
Charlotte Flitcraft, Contract Specialist
Procurement and Grants Office
Centers for Disease Control and Prevention
2920 Brandywine Road, Room 3000
Atlanta, GA 30341-4146
Telephone number: 770-488-2632
E-mail address: caf5@cdc.gov

For program technical assistance, contact:
Component 1 - Comprehensive State-Based Tobacco Use
Prevention and Control Programs
Dianne May, Program Services Branch
Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Hwy, N.E., MS K50
Atlanta, GA 30341
Telephone number: (770) 488-1104
E-mail address: dmay@cdc.gov

Component 2 - State Nutrition and Physical Activity Programs to Prevent Obesity and Other Chronic Diseases Robin Hamre, Obesity Prevention Programs Team Leader
Division of Nutrition and Physical Activity
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention
4770 Buford Hwy., NE, MS K24
Atlanta, GA 30341
Telephone number: (770) 488-6050
E-mail address: rwh9@cdc.gov

Component 3 - WISEWOMAN
Julie C. Will, PhD, MPH

WISEWOMAN Team Leader
Division of Nutrition and Physical Activity
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention
4770 Buford Hwy., NE, MS K26
Atlanta, GA 30341
Telephone number: (770) 488-6024
E-mail address: jxw6@cdc.gov
For WISEWOMAN Definitions see WISEWOMAN Guidance Document: Interpretation of Legislative Language and Existing Documents at http://www.cdc.gov/wisewoman**.**

Component 4 - State Based Oral Disease Prevention Programs
Kathleen Heiden, RDH, MSPH
Division of Oral Health
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention
4770 Buford Hwy., NE, MS F10
Atlanta, GA. 30341
Telephone number: (770) 488-6056
E-mail address: orhealthgrants@cdc.gov

Component 5 - Arthritis
Sakeena Smith
Division of Adult and Community Health
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention
4770 Buford Hwy., NE, MS K66
Atlanta, GA 30341-3717
Telephone (770) 488-5440
E-mail address: szs4@cdc.gov

Component 6 – BRFSS
Ruth Jiles
Division of Adult and Community Health
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention
4770 Buford Hwy., NE, MS K66
Atlanta, GA 30341-3717
Telephone (770) 488-2542
E-mail address: Rjiles@cdc.gov

Component 7 - Chronic Disease Genomics
Ann Malarcher
Division of Adult and Community Health
National Center for Chronic Disease Prevention and Health Promotion
Center For Disease Control and Prevention

4770 Buford Hwy., NE, MS K47
Atlanta, GA 30341
Telephone: (770) 488-8006
E-mail address: aym8@cdc.gov
Dated:

_____
Sandra R. Manning, CGFM
Director,
Procurement and Grants Office
Centers for Disease Control and Prevention (CDC)

K. Appendices
Relevant to WISEWOMAN Component:
Appendix A: Eligibility

	Competitive		Funding Level		Type of Program	
Applicant	Yes	No	1st	2nd	Standard	Enhanced
States						
Alabama	X		X		X	X
Alaska	X		X		X	X
Arizona	X		X		X	X
Arkansas	X		X		X	X
California		X		X		X
Colorado	X		X		X	X
Connecticut		X		X	X	
Delaware	X		X		X	X
Florida	X		X		X	X
Georgia	X		X		X	X
Hawaii	X		X		X	X
Idaho	X		X		X	X
Illinois		X		X		X
Indiana	X		X		X	X
Iowa		X		X		X
Kansas	X		X		X	X
Kentucky	X		X		X	X

Louisiana	X		X		X	X
Maine	X		X		X	X
Maryland	X		X		X	X
Massachusetts		X		X	X	
Michigan		X		X	X	
Minnesota	X		X		X	X
Mississippi	X		X		X	X
Missouri	X		X		X	X
Montana	X		X		X	X
Nebraska		X		X	X	
Nevada	X		X		X	X
New Hampshire	X		X		X	X
New Jersey	X		X		X	X
New Mexico	X		X		X	X
New York	X		X		X	X
North Carolina		X		X		X
North Dakota	X		X		X	X
Ohio	X		X		X	X
Oklahoma	X		X		X	X
Oregon	X		X		X	X
Pennsylvania	X		X		X	X

Rhode Island	X		X		X	X
South Carolina	X		X		X	X
South Dakota		X		X	X	
Tennessee	X		X		X	X
Texas	X		X		X	X
Utah	X		X		X	X
Vermont		X		X	X	
Virginia	X		X		X	X
Washington	X		X		X	X
Washington, D.C.	X		X		X	X
West Virginia	X		X		X	X
Wisconsin	X		X		X	X
Wyoming	X		X		X	X
Territories						
Applicant	Competitive		Funding Level		Type of Program	
	Yes	No	1st	2nd	Standard	Enhanced
American Samoa	X		X		X	X
Guam	X		X		X	X
N. Mariana Islands	X		X		X	X
Puerto Rico	X		X		X	X

Republic of Palau	X		X		X	X
Virgin Islands	X		X		X	X
Tribes Tribes						
Arctic Slope	X		X		X	X
Cherokee Nation	X		X		X	X
Cheyenne River	X		X		X	X
Consolidated Tribal Health	X		X		X	X
Hopi	X		X		X	X
Indian Community Health	X		X		X	X
KAW Nation	X		X		X	X
NARA	X		X		X	X
Navajo	X		X		X	X
Poach Band	X		X		X	X
South Puget	X		X		X	X
South-Central		X		X		X
Southeast Alaska		X		X	X	
Yukon-Kuskokwim	X		X		X	X
All other Programs funded by NBCCEDP	X		X		X	X
All other programs not funded by NBCCEDP	Not eligible					

Appendix B-Type of Program and Performance Requirements

Depending on type of program and level of funding, a project is expected to complete the performance activities detailed in the appropriate cell.

Funding Level	Type of Program and Performance Requirements	
	Standard Demonstration Project (Available for applicants applying in FY 2003 and FY 2004) **Standard Best Practices Project** **(Available in FY 2005 and later)**	Enhanced **(Available for applicants applying in FY** **2003 and later**
First **Annual Funding:** **$50,000 to $250,000 (Standard);** **$250,000 to $500,000 (Enhanced).**	1) Complete Program Startup Activities found in checklist* 2) Test activities using pilot study methods 3) Screen 500 women annually for blood pressure and cholesterol and provide all with health education 4) Ensure at least 60 percent of newly screened women receive complete lifestyle intervention program 5) If applying in FY 2005 or later, programs must implement WISEWOMAN-recommended best practices (recommendations available in FY 2005).	1) Complete Program Startup Activities found in checklist including IRB protocols* 2) Receive IRB approval 3) Test methods in pilot study that includes screening and intervention activities 4) Demonstrate adequate power to test effectiveness of lifestyle interventions in a full-scale study 5) Prepare publishable manuscript
Second **Annual Funding:** **$250,000 to $750,000 (Standard);** **$750,000 to $1,250,000 (Enhanced)** **Funding level for Standard and Enhanced Programs depends on success in meeting or exceeding performance requirements.**	1) Screen at least 2500 women each year for blood pressure and cholesterol and provide all with health education** 2) Ensure at least 60 percent of new women receive complete lifestyle intervention. 3) Demonstrate that newly enrolled participants adopt a healthier lifestyle during the year following enrollment** 4) Demonstrate that at least one quarter of women screened are newly detected with high blood pressure or high cholesterol.** 5) Demonstrate a reduction in expected coronary heart disease deaths per 1000 women expected in 10 years***	1) Screen and intervene with enough women to achieve statistical power as determined during 1st level 2) Ensure 75 percent of eligible women in intervention group receive complete intervention 3) Demonstrate that intervention group adopts a healthier lifestyle during the year following enrollment** 4) Demonstrate statistically significant difference on one key outcome 5) Develop monograph and/or training on methods to help other projects adopt successful program 6) Submit at least one manuscript on methods and results to a peer-reviewed journal

*Program Start-Up Checklist developed by the North Carolina WISEWOMAN program is found on page 18 of the monograph "Integrating Cardiovascular Disease Prevention into Existing Health Services: The Experience of the North Carolina WISEWOMAN Program" at http://www.hpdp.unc.edu/wisewoman/manual.htm.
**See GPRA measures developed May 17, 2002 found in WISEWOMAN Guidance Document: Interpretation of Legislative Language and Existing Documents at http://www.cdc.gov/wisewoman.
***Use Framingham risk formulation that includes smoking, systolic blood pressure, total cholesterol, and age. This is calculated from minimum data elements.

Appendix C

Framework for Performance Measures of
Nutrition & Physical Activity Programs to Prevent Obesity & Chronic Diseases

Click on Appendix C to see table.

Appendix D

Eligibility for Program Announcement 03022 Chronic Disease Prevention and Health Promotion Programs

Component 1: State-Based Basic Implementation Tobacco Prevention and Control Programs

Applications received from current grant recipients under:
Program Announcement 99038, Comprehensive State-Based Tobacco Use Prevention, and Control Programs, will be funded upon receipt and approval of a technically acceptable application.

Component 3: Well-Integrated Screening and Evaluation for Women Across the Nation

Applications received from current grant recipients under
Well Integrated Screening and Evaluation for Woman Across the nation (WISEWOMAN):
Program announcement 00115 WISEWOMAN
Program Announcement 99135 WISEWOMAN
Program Announcement 01098 WISEWOMAN Enhanced, will be funded upon receipt and approval of a technically acceptable application.

Component 4: State-Based Oral Disease Prevention Program

Applications received from current grant recipients under:
Program Announcement 01046 Support State Oral Disease Prevention Programs, will be funded upon receipt and approval of a technically acceptable application.

Component 5: Arthritis

Applications received from current grant recipients under:
Program Announcement 01097 Reducing the Impact of Arthritis and Other Rheumatic Conditions, will be funded upon receipt and approval of a technically acceptable application.

Component 6: Behavioral Risk Factor Surveillance Systems (BRFSS)

Applications received from current grant recipients under:

Program Announcement 99044 Behavioral Risk Factor Surveillance System (BRFSS), will be funded upon receipt and approval of a technically acceptable application.

AR-1
Human Subjects Requirements
If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects. All awardees of CDC grants and cooperative agreements and their performance sites engaged in human subjects research must file an assurance of compliance with the Regulations and have continuing reviews of the research protocol by appropriate institutional review boards.
In order to obtain a Federalwide Assurance (FWA) of Protection for Human Subjects, the applicant must complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. OHRP will verify that the Signatory Official and the Human Subjects Protections Administrator have completed the OHRP Assurance Training/Education Module before approving the FWA. Existing Multiple Project Assurances (MPAs), Cooperative Project Assurances (CPAs), and Single Project Assurances (SPAs) remain in full effect until they expire or until December 31, 2003, whichever comes first.
To obtain a FWA contact the OHRP at:
http://ohrp.osophs.dhhs.gov/irbasur.htm OR
If your organization is not Internet-active, please obtain an application by writing to:
Office for Human Research Protections (OHRP)
Department of Health and Human Services
6100 Executive Boulevard, Suite 3B01, MSC 7501
Rockville, Maryland 20892-7507
(Note: For Express or Hand Delivered Mail, Use Zip Code 20852)
Note: In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

AR-2
Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

AR-7
Executive Order 12372 Review
Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (E.O.) 12372. The order sets up a system for State and local governmental review of proposed Federal assistance applications. Applicants should contact their State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications and to receive instructions on the State process. For proposed projects serving more than one State, the applicant should contact the SPOC for each State affected. Click on the following link to get the current SPOC list
http://www.whitehouse.gov/omb/grants/spoc.html
SPOCs who have recommendations about the State process for applications submitted to CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to the Grants Management Specialists listed above in the program announcement.
If Indian tribes are eligible applicants for the above program announcement, SPOCs or tribal governments that have recommendations about an application submitted to CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to the Grants Management Specialist listed in the program announcement listed above.
CDC does not guarantee to accept or justify its nonacceptance of recommendations that are received more than 60 days after the application deadline.

AR-8
Public Health System Reporting Requirements
This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:
A. A copy of the face page of the application (SF 424).
B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
A description of the population to be served;
A summary of the services to be provided; and
A description of the coordination plans with the appropriate state and/or local health agencies.
If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

AR-9
Paperwork Reduction Act Requirements
Projects that involve data collection from 10 or more persons and that are funded by grants and cooperative agreements will be subject to review and approval by the Office of Management and Budget (OMB).

If required information is being collected from 10 or more persons for a cooperative agreement and CDC has not received OMB approval, under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).
If required information is being collected from 10 or more persons for a grant and CDC has not received OMB approval, under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant will be subject to review and approval by the Office of Management and Budget (OMB).
If OMB approval has been obtained for data collection resulting from this program, insert the following with requested information completed.
Data collection initiated under this grant/cooperative agreement) has been approved by the Office of Management and Budget (OMB) under OMB number (0920-xxxx for CDC and 0923-xxxx for ATSDR), (insert title of clearance request), (insert expiration date).
If OMB clearance is pending for data collection resulting from this program, insert the following statement:
OMB clearance for the data collection initiated under this grant/cooperative agreement is pending approval by OMB.

AR-10
Smoke-Free Workplace Requirements
CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

AR-11
Healthy People 2010
CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. For the conference copy of "Healthy People 2010," visit the internet site: http://www.health.gov/healthypeople.

AR-12
Lobbying Restrictions
Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local

legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation
It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

CDC Home Page: http://www.cdc.gov
CDC Funding Web Page: http://www.cdc.gov/od/pgo/funding/funding.htm
CDC Forms Web Page: http://www.cdc.gov/od/pgo/forminfo.htm

Appendix E

Program Start-Up Checklist

Appendix E
WISEWOMAN Program Start-up Checklist

√	Responsibilities		WISEWOMAN Program Start-up Checklist
	State	Local	
Project Administration Tasks			
❒			1. Hire/identify staff to plan and administer program.
❒			2. Establish and convene an advisory committee to assist with screening and intervention development.
❒			3. Establish program guidelines, based on CDC requirements: • Target population/eligibility requirements. • Services to be provided and protocols. • Use of program funds. • Reporting requirements.
❒			4. Submit program protocols to CDC for approval. Enhanced projects must also receive Institutional Review Board approval.
❒			5. Develop plan to identify/select clinics to implement program at local level (e.g., competitive application process).
❒			6. Establish contracts between state and local clinics for program implementation.
❒			7. Establish payment/reimbursement system between state and local clinics.
❒			8. Establish contracts between state and collaborative partners.
Project Development Tasks			
❒			1. Establish protocols for CVD clinical services .
❒			2. Plan CVD intervention strategy and identify/develop intervention materials for participants.
❒			3. Develop program evaluation plans.
❒			4. Develop program forms and letters: • Participant informed consent form. • Medical release form. • Physician referral form. • Clinical follow-up letters to physicians. • Clinical follow-up letters to participants.

√	Responsibilities		**WISEWOMAN Program Start-up Checklist**
	State	Local	
			• Participant enrollment, baseline screening, and follow-up forms.
❒			5. Create centralized database to house participant data from local clinics.
❒			6. Develop participant tracking system to ensure timely follow-up of clinic visits, medical referrals, and intervention visits.
❒			7. Develop program manual of administrative policies, clinical protocols, quality assurance, and educational resources for local clinics.
❒			8. Develop training curriculum on program implementation for local clinics.
❒			9. Identify clinical laboratory services.
❒			10. Identify physicians in community to partner with program and accept medical referrals; contract with physicians to provide care.
Project Start-up Tasks			
❒			1. Identify clinic space needed for delivery of clinical services and behavioral intervention.
❒			2. Train all staff involved with the administration/ implementation of the program at local clinics.
❒			3. Ensure that local clinics have all necessary program materials for program start-up (e.g., intervention materials, consent forms, participant baseline screening and clinical follow-up forms).
❒			4. Conduct participant recruitment and community outreach activities.
❒			5. Enroll participants and begin providing clinical and intervention services.

Source: Adapted from North Carolina's WISEWOMAN Program Start-up Checklist (University of North Carolina, 2001, p. 18).

Appendix *F*

Orientation for New Project Staff

Appendix F
Orientation to WISEWOMAN

The WISEWOMAN project officer will provide an orientation of the program to newly funded WISEWOMAN project staff within 90 days of the award. The preferred method for this type of in-depth orientation is through a site visit.

Depending on the situation, the WISEWOMAN project officer may also want to conduct an orientation site visit with a new program director or project coordinator who has been hired into an existing WISEWOMAN project.

If this is a **newly funded** WISEWOMAN project, the project officer will want to make sure that the staff members have access to copies of the following materials:

- WISEWOMAN guidance document, *The Heart of the Matter*.
- North Carolina's WISEWOMAN monograph.
- Minimum Data Elements (MDE) User's Guide.
- Success Stories documents.
- WISEWOMAN *Journal of Women's Health* supplement.

If the orientation is to a new coordinator in an established WISEWOMAN project, make sure that she or he has a copy of Program Announcement 03022 (component 3—WISEWOMAN; see Appendix D), and review the recipient activities and other pertinent sections of this announcement.

Important Web Sites

- http://wisewoman.forum.cdc.gov
- http://wisewoman.rti.org
- http://www.hpdp.unc.edu/nph/

User IDs and passwords are needed to access the WISEWOMAN/Research Triangle Institute (RTI) Web site and the WISEWOMAN Web forum.

The following list of topics was created to be used by the project officer during the orientation site visit.

No.	Source	Topic
1.	L	Organizational charts (agency, center, division, CDC Futures Initiative)
2.	P	Document that describes what you can expect from your CDC WISEWOMAN project officer (may want to discuss this at the beginning of the orientation)

3.	L	History of WISEWOMAN
4.	B	Component 3 of the Request for Applications (RFA)—focus on recipient activities
5.	B/P	Performance indicators
6.	P	Important dates
7.	B	Suggested Progress Report format (see RFA for guidance; the current guidance document needs to be revised)
8.	GD	Executive Summary from the guidance document (review each and every policy with the new project staff)
9.	GD*	Start-up Checklist
10.	GD*	List of protocols located in the guidance document
11.	B/L	At-a-Glance document and other WISEWOMAN publications
12.	P/L	Data User's Manual (in a three-ring binder)
13.	L	Resources and publications that include information on the Nutrition and Public Health Course
14.	L/B	Summary of other WISEWOMAN projects (go to Web site or refer to *Journal of Women's Health* supplement)
15.	P/L	Institutional Review Board (IRB) information for enhanced projects

B/P = Bring/Provide.
GD = WISEWOMAN guidance document, *The Heart of the Matter*.
L = Link to URL.
* Might be unnecessary to review with established projects.

Appendix G

Consent Forms

Appendix G
Consent Form Checklist for Standard WISEWOMAN Projects*

To assist standard projects in developing a consent form that addresses the activities of the WISEWOMAN program, the following checklist was developed. The *italicized statements* provide an example of how a project may decide to convey this information.

* Enhanced (research) projects should refer to CDC's Web site for Human Subject Research, which contains information about consent forms at http://www.cdc/od/ads/hrs2.htm.

REQUIRED ELEMENTS	Check
Purpose and procedures of program *I agree to be in the (name of) program. This program has been designed to help women reduce their risk for heart disease and other chronic diseases. This program provides **free** screening tests and a coach who will contact me to talk about easy ways to eat smart, be fit, and live well.*	
List of screening tests *I agree to have my height, weight, waist circumference, blood pressure, cholesterol, and glucose measured/tested. In addition, I understand that I will be asked some medical history and health behavior questions.*	
Comment about **side effects/discomfort** of lab tests *The screening tests and possible side effects or discomfort have been explained to me.*	
Return one year later *I understand that I will be asked to return one year from now, even if my screening results were normal, to complete the same tests and paperwork again. It is very important that I return for this second office visit, because the information will be used to figure out if this program was useful.*	

Obligation to refer women with abnormal screening results	
Physical activity clearance may be needed prior to receiving information on increasing physical activity.	
*I may **drop out** of this program at any time.*	
Confidentiality statement	
Contact info for questions	
OTHER CONSIDERATIONS	
Eligibility criteria	
Billing responsibility	
A statement about sharing information with doctor, health department, and the Centers for Disease Control and Prevention	
Health Insurance Portability and Accountability Act (HIPAA) info is usually included separately from the consent form, because there may be revisions needed for the consent form but not needed for the HIPAA.	
Many WISEWOMAN projects and Breast and Cervical Cancer Early Detection Programs use the same (one) consent form, which is especially useful if the programs want to provide comprehensive services in a "one-stop" manner.	

Appendix H

Sample Work, Training, and Evaluation Plan

Appendix H

WISEWOMAN Work, Training, and Evaluation Plan

Projects may use the template provided in this document to meet the requirement of submitting a work, evaluation, and training plan for the WISEWOMAN program.

Work plan: The goals of your project should be linked to the goals of the WISEWOMAN program. Each objective in your work plan should be monitored and evaluated to determine quality, success, and/or effectiveness. SMART (Specific, Measurable, Achievable, Relevant, Time Based) objectives should be written to meet goals.

Training plan: Your project is required to provide an annual training plan for your staff/contractors/volunteers with a focus on achieving the program's performance indicators and meeting reporting requirements. The training plan should include the following elements: training topics, training objectives, training participants, and training schedule. You can fulfill the training plan requirement by incorporating the above elements into one of your professional development objectives.

Evaluation plan: To help you think through the evaluation aspects of your work plan, you should refer to CDC's Framework for Program Evaluation in Public Health (http://wisewoman.forum.cdc.gov). Information from this framework is also provided in the evaluation chapter of the WISEWOMAN guidance and resource document.

A definition of key terms (e.g., goal, measure of success, objectives) and a blank template are found at the end of this document.

Sample WISEWOMAN Work & Evaluation Plan*	
Project Name: Live and Eat Well	**Budget Period: June 30, 2006 – June 29, 2007**
* The goals, objectives, and performance indicators listed in this sample are especially relevant to a standard (public health practice) WISEWOMAN project that receives level two funding.	
Screening Project Goal: Increase the number of eligible women who complete CVD risk factor screening	**Measure of Success for Objective:** An additional 500 eligible women (40–64 years old and enrolled in BCCEDP) will complete CVD risk factor screening, for a total of 1000 new women screened. (2500 women in total will be screened this year: 1000 new woman and 1500 women who will return for their annual screening visit.)

WISEWOMAN Program Goal: To build a national WISEWOMAN program that provides every eligible BCCEDP woman with an opportunity for WISEWOMAN services. (Reach, Goal #1)		**CDC Performance Indicator for Screening:** At least 2500 women will be screened and receive risk reduction counseling each year.		
Objective	**Activities**	**Data**	**Time frame for assessing progress**	**Person responsible**
By April 2007 the WISEWOMAN coordinator will work with 24 providers who screen at least 50 women for BCCP (and are 40–64 years of age) to identify strategies that help them screen at least 80% of these eligible women for CVD risk factors too.	***Here you provide a brief description of your activity.***	MDEs	December 2006	Data manager
	Here you provide a brief description of your activity.	***List data source you will use to determine progress made***	February 2007	Coordinator
	Here you provide a brief description of your activity.	MDEs	April 2007	Data manager
Lifestyle Intervention Project Goal: Increase the number of eligible women who complete the lifestyle intervention.		**Measure of Success for Objective:** This means that 900 of the 1200 newly screened women in 2005 will attend at least one lifestyle intervention (LSI) session and 720 of the same 1200 women will complete all sessions. Last year 60% (600/1000) of the newly screened women attended at least one LSI session and 50% (500/1000) completed all of the LSI sessions.		

WISEWOMAN Program Goal: To establish a WISEWOMAN program where at least 60–75% of the women newly screened receive the lifestyle intervention. (Reach, Goal #2)		**CDC Performance Indicators for LSI:** 75% of the new women screened will attend one LSI session and 60% will complete all LSI sessions.		
Objective	**Activities**	**Data**	**Time frame for assessing progress**	**Person responsible**
The health education specialist will provide outreach workers with additional resources that will be used to encourage newly screened women to complete the LSI sessions within this budget period.	***Here you provide a brief description of your activity.***	MDEs	July 2006	Data manager
	Here you provide a brief description of your activity.	***List data source you will use to determine progress made***	August 2006	Health education specialist
	Here you provide a brief description of your activity.	***List data source you will use to determine progress made***	February 2007	Health education specialist
	Here you provide a brief description of your activity.	MDEs	April 2007	Data manager
Supporting and Tracking Participants Project Goal: Increase the number of women who return for the evaluation (first annual) screening visit.		**Measure of Success for Objective:** 900 of the 1200 newly screened women in 2005 will complete the evaluation (first annual) screening visit. Last year 60% of the newly screened women (600/1000) completed this screening visit.		

WISEWOMAN Program Goal: To establish a WISEWOMAN program that improves CHD risk scores. (Effectiveness, Goal #2)		**CDC Performance Indicators for first annual screening visit:** At least 75% of newly screened WISEWOMAN participants will complete the first annual re-screening visit (within 10–14 months from baseline screening). This is required for purposes of program evaluation (i.e., these data are needed to determine if the program improves CHD risk scores).		
Objective	**Activities**	**Data**	**Time frame for assessing progress**	**Person responsible**
The coordinator will work with providers to ensure that they have properly working systems in place to track and remind women that they need to complete their first annual screening visit.	***Here you provide a brief description of your activity.***	MDEs	August 2006	Data manager
	Here you provide a brief description of your activity.	***List data source you will use to determine progress made***	October 2006	Coordinator
	Here you provide a brief description of your activity.	MDEs	February 2007	Data manager

Defining Terms

Goal: Goals provide a general "big picture" statement of outcomes the project intends to accomplish to help fulfill its mission. Over the next 1–3 years, what do you want to accomplish? Each project goal should be linked to a WISEWOMAN program goal.

Measures of Success: Measures of success are standards that are established to measure progress in achieving project goals. They should help answer the question, "How will we know if our project has achieved this goal?" Measures of success should be significant and truly gauge success in attaining the goal. They should contain a numeric value or observable behavior. Because goals are broad, multiple measures of success may be required to fully assess progress toward a particular goal.

Objectives state the "big steps" a project will take to attain its goal. To write an objective, it might be helpful to begin with a word that describes the direction of the desired accomplishment (e.g., to increase, to decrease). Objectives should be S.M.A.R.T., that is, **s**pecific (identify who, what, and where), **m**easurable (identify how many by when), **a**chievable (can be attained), **r**ealistic (can be attained given time and resources available), and **t**ime framed (identify when).

Activities or **strategies** describe the actions needed to accomplish the objective. Some people find it helpful to begin their strategy statement with an action word (e.g., establish, promote, develop, prepare, create, analyze, investigate, initiate, survey).

Potential Data Sources are pieces of information that can be used to assess program activities or outcomes. This information can be obtained from the MDEs, BRFSS, and other data sources that include data gathered from medical records, interviews, training materials, focus groups, observations, census data, etc.

Time Frame for Assessing Progress refers to the time when the person responsible will check the progress of the activity and determine or evaluate if course correction is needed.

Responsible Person or Partner is who will be the one seeing that the activity is accomplished.

WISEWOMAN Work, Training and Evaluation Plan Template

Project Goal:			**Measure of Success:**	
WISEWOMAN Program Goal:			**CDC Performance Indicator:**	
Objective	**Activities**	**Data**	**Time frame for assessing progress**	**Person responsible**

The format for this sample work plan was adapted from the NBCCEDP guidance, *Workplans: A Program Management Tool* (http://www.cdc.gov/cancer/nbccedp/training/workplans/). CDC's *Framework for Program Evaluation in Public Health* document (http://www.cdc.gov/eval/framework.htm) should also be referred to when developing your WISEWOMAN work and evaluation plan.

Appendix I

Sample Budget

Appendix I
Sample Budget

This is a sample format of a WISEWOMAN budget summary. Projects will provide detailed budget justification in a separate document. A blank version of this format/template may be accessed from the WISEWOMAN Web board.

Proposed Budget FY2006 (June 30, 2005–June 29, 2006)

Amt. Req. = Amount Requested from Federal Funds

TOTAL FEDERAL 667,376

A. PERSONNEL

Salaries

Name	Position Title*	Annual Salary	Percentage of Time	Months	Amount Requested	0.6	0.4
Jane Smith	Program Coordinator	50,000.0	1.0	12.0	50,000.0		50,000.0
New Position	Intervention Specialist	40,000.0	1.0	9.0	30,000.0	10,000.0	20,000.0
Julie Smith	Sr. Off. Support Assist.	25,000.0	0.6	12.0	15,000.0		15,000.0
Joe Smith	Office Support Assist.	20,000.0	0.1	12.0	2,000.0		2,000.0
Jennifer Smith	NW Dist. Case Mgr.	40,000.0	0.1	12.0	4,000.0	3,200.0	800.0
Jack Smith	QA Assistant	37,000.0	0.1	12.0	3,700.0		3,700.0
Jasmine Smith	Pub. Ed Coordinator	30,686.0	0.1	12.0	3,068.6		3,069.0
Bill Jones	Data Coordinator	55,000.0	0.4	12.0	22,000.0	11,000.0	11,000.0
Bruce Jones	Office Support Assist.	20,404.0	0.4	12.0	8,161.6		8,162.0
Brenda Jones	Office Support Assist.	19,107.0	0.1	12.0	1,910.7		1,911.0
Bobby Jones	Screening Coordinator	32,008.0	0.1	12.0	1,600.4		1,600.0
Beverly Jones	Screening Assistant	26,120.0	0.1	12.0	1,306.0		1,306.0
New Position	Comp. Info Tech Spec. II	48,042.0	0.1	12.0	4,804.2		4,804.0
Total Salaries			4.10 FTE†		**147,551.5**	24,200.0	123,352.0

Personnel 147,551.5

* Project to provide CDC with brief description of duties and responsibilities for each position in the budget justification document. If position is vacant, please provide estimated time of hire.

† FTE = full-time equivalent employees.

B. FRINGE BENEFITS

Salaries	Fringe %	Total
147,551.5	33.0	**48,692.0**

0.6	**0.4**
7,986.0	40,706.2

Fringe **48,692.0**

C. TRAVEL

In State

Travel for Project Staff to conduct provider site visits and trainings.

20/trips x 2/person x 360/miles x $.345/mile	4,968.0
Subtotal	4,968.0

Amt. Req.	**0.6**	**0.4**
4,968.0		4,968.0

Travel for 1 Case Manager to perform job responsibilities.

3/trips x 1 person x 150/miles x $.345/mile	155.0
Subtotal	155.0

Amt. Req.	**0.6**	**0.4**
155.0		155.0

Travel for Intervention Specialist to perform maintenance and support activities.

20/trips x 1 person x 360/miles x $.345/mile	2,484.0
Subtotal	2,484.0

Amt. Req.	**0.6**	**0.4**
2,484.0		2,484.0

Out of State

Travel for Program Staff to the Nutrition and Public Health Course Conference as required by grant; fees include room, meals, and gratuities.

1/trip x 1/person x $500/airfare	500.0
1/trip x 1/person x 240/miles x $.345/mile	83.0
parking x 1 person x $8/day x 7 days	56.0
ground transportation x 1 person x $50/trip	50.0
1/conf. fees x 1/person x $1,200	1,200.0
Subtotal	1,889.0

Amt. Req.	**0.6**	**0.4**
1,889.0		1,889.0

Travel for WISEWOMAN semi-annual Project Directors' meetings, as required by grant.

2/trips x 2/persons x $500/airfare	2,000.0
2/trips x 2/persons x 240/miles x $.345/mile	331.0
2 x parking x 2 persons x $8/day x 6 days	192.0
6/days x 2/person x $50/meals/day	600.0
6/nights lodging x 2/person x $120/night	1,440.0
2/ground transport x 2/person x $50/trip	200.0
Subtotal	4,763.0

Amt. Req.	**0.6**	**0.4**
4,763.0		4,763.0

Travel for the Data Manager's meeting, as required by grant.

1/trip x 2/person x $500/airfare	1,000.0
1/trip x 2/person x 240/miles x $.345/mile	166.0
parking x 2 persons x $8/day x 3 days	48.0
3/days x 2 persons x $50/meals/day	300.0
ground transportation x 2 persons x $50/trip	100.0
Subtotal	1,614.0

Amt. Req.	**0.6**	**0.4**
1,614.0		1,614.0

Travel for the CVH Conference (for professional development).

1/trip x 2/person x $500/airfare	1,000.0
1/trip x 2/person x 240/miles x $.345/mile	166.0
parking x 2 persons x $8/day x 3 days	48.0
3/days x 2 persons x $50/meals/day	300.0
ground transportation x 2 persons x $50/trip	100.0
Subtotal	1,614.0

Amt. Req.	**0.6**	**0.4**
1,614.0		1,614.0

17,487.0		17,487.0	**Travel**	**17,487.0**

D. EQUIPMENT

If WISEWOMAN funds are used to purchase equipment, please provide quantity and item name (e.g., fax machine, computer) along with justification.

Amt. Req.	**0.6**	**0.4**		
0.0	0.0	0.0	**Equipment**	**0.0**

E. SUPPLIES

				Amt. Req.	0.6	0.4		
General office supplies for program operation (expendable supplies)								
@ $300/FTE x 4.10 FTEs			1,230.0	1,230.0		1,230.0		
Educational materials to be used at community events				1,000.0		1,000.0		
Educational Materials / Reinforcers	Cost/Each	Quantity	Total					
Notebook binder	2.0	545.0	1,090.0	1,090.0	1,090.0			
Lifestyle Intervention Notebook printing	6.0	545.0	3,270.0	3,270.0	3,270.0			
Nutrition reinforcer—cookbook	3.2	545.0	1,744.0	1,744.0	1,744.0			
Physical activity reinforcer—theraband	3.0	545.0	1,635.0	1,635.0	1,635.0			
Physical activity reinforcer—pedometer	11.6	463.0	5,370.8	5,370.8	5,371.0			
			13,109.8	**15,339.8**	13,110.0	2,230.0	**Supplies**	**15,339.8**

F. CONTRACTUAL

For each contractor, the project will provide CDC with (1) the name of the contractor, (2) method of selection, (3) period of performance, (4) description of activities, (5) method of accountability, and (6) itemized budget with narrative justification. For table 1 for sample clinical and intervention service budget justification.

	Amt. Req.	0.6	0.4		
Clinical providers	225,170.8	225,170.8			
Lifestyle intervention providers	117,693.8	117,693.8			
University Outreach & Extension services (maintenance)	10,000.0	10,000.0			
OATS Transportation	500.0	500.0			
UGA School of Nursing (evaluate project)	2,000.0		2,000.0		
Marketing company to do public education campaign	5,000.0		5,000.0		
Translation services	1,000.0	1,000.0			
Training for screening & intervention services	1,000.0		1,000.0		
	362,364.6	354,364.6	8,000.0	**Contractual**	**362,364.6**

G. CONSTRUCTION

Amt. Req.	0.6	0.4		
0.0	0.0	0.0	**Construction**	**0.0**

H. OTHER COSTS

	Amt. Req.	0.6	0.4
Printing			
14,000 Patient History Forms; 100 Spanish Patient History Forms ($150); Misc. Projects ($100) +	250.0	150.0	100.0
Provider Manuals ($250)	250.0	250.0	
Promotional and educational printing ($250)	750.0	500.0	250.0
Network charges (based on 2.91 users @ $2,000 ea.)	5,820.0		5,820.0
Voicemail fees (based on 2.91 FTEs @ $48 ea.)	140.0		140.0
Postage	60.0	60.0	
Public service announcements	8,000.0	0.0	8,000.0
	15,270.0	960.0	14,310.0

Other **15,270.0**

I. TOTAL DIRECT CHARGES (sum A–H)

Direct **606,704.8**

J. INDIRECT CHARGES (Administrative Expenses)

Public Law 101–354 requires programs to spend no more than 10% of the federal monies for administrative expenses. The 10% limitation on administrative costs is in lieu of indirect costs.

Indirect **60,671.0**

K. TOTALS (sum I and J)

667,376

SUMMARY OF 60% / 40% DISTRIBUTION

Source	**60%**	**40%**	Totals	
A. Personnel salaries	24,200.0	123,352.0	147,552.0	
B. Fringe	7,986.0	40,706.2	48,692.2	
C. Travel	0.0	17,487.0	17,487.0	
D. Equipment	0.0	0.0	0.0	
E. Supplies	13,110.0	2,230.0	15,340.0	
F. Contractual	354,364.6	8,000.0	362,364.6	
G. Construction	0.0	0.0	0.0	
H. Other costs	960.0	14,310.0	15,270.0	
SUBTOTAL	**400,620.6**	**206,085.2**	**606,705.7**	
I. Direct costs (sum A–H)				**606,705.7**
J. Indirect costs				**60,671.0**
K. Total federal funds requested				**667,376.7**
	0.66	**0.34**		

(difference in 60/40 summary total and total requested is due to rounding)

Table 1. Screening and Intervention Services based on estimated 2,500 participants

	State Medicare Rate	Number	Total	CPT
Screening Services				
Office Visit				
Initial	48.9	625.0	30,550.0	99,396.0
Annual	48.9	1,875.0	91,650.0	99,396.0
15-minute problem-focused visit	35.6	800.0	28,440.0	99,213.0
15-minute consultation	46.7	400.0		99,241.0
Routine venipuncture collection of specimen	5.0	2,500.0	12,500.0	
Lipid panel (TC*,HDL†, LDL‡, triglycerides)—fasting	18.7	2,000.0	37,440.0	
Cholesterol, serum or whole blood, total—nonfasting	6.1	500.0	3,040.0	
HDL-C—nonfasting	11.4	500.0	5,720.0	
A1C	13.6	200.0	2,712.0	
Blood glucose, quantitative	5.5	2,000.0	10,960.0	
Glucose tolerance test (GTT), three specimens	18.0	120.0	2,158.8	
			225,170.8	
Lifestyle Intervention Services				
Initial intervention session w/goal setting	32.0	1,875.0	60,000.0	
Reassessment and intervention (ea. 15 min. individual and face-to-face) x 16.79	16.8	1,875.0	31,481.3	
Reassessment and intervention (group face-to-face) x 6.99 / 30 min. x 2	14.0	1,875.0	26,212.5	
Intervention coordination	5.0	1,875.0	9,375.0	
			117,693.8	

* total cholesterol.
† high-density lipoprotein cholesterol [HDL-C].
‡ low-density lipoprotein cholesterol [LDL-C].

MATCHING FUNDS REQUIREMENT

1 to 3 Match: Matching funds may be cash, in-kind, or donated services or equipment. Contributions may be made directly or through donations from public or private entities. Public Law 93-638 authorizes tribal organizations contracting under the authority of Title 1 to use funds received under the Indian Self-Determination Act as matching funds.

All costs used to satisfy the matching requirements must be documented by the applicant and will be subject to audit. Specific rules and regulations governing the matching fund requirement are included in the Code of Federal Regulations (CFR) 45 Part 92, subpart C, section 92.24. Matching funds are not subject to the 60/40 requirements.

Match Ideas

- Uncompensated care: Use the difference between customary fees for screening services and what Medicare, Part B allows.
- Organization (such as AHA, state association of health plans, parks and rec) provides public education, incentives (e.g., pedometers, cookbooks), materials/literature, mailings, staff time, professional education, etc. to promote or address the needs of the WISEWOMAN population.
- Donated media time for public education.
- Require that the local agency provide a match.
- If uncompensated, document participants' time spent in trainings and advisory meetings as in-kind contribution.

Appendix J

Sample Project Summary Report

Appendix J
WISEWOMAN Project Summary Report

Using the Minimum Data Elements to Inform Stakeholders of Progress
and to Assist with Project Management
Data through December 31, 2004

Date of the Report: June 23, 2005

Project:	**All Projects**	
Screening Data Begins:	**February 2000**	**MA**
	October 2000	**SCF**
	January 1998	**NC**
	Sep-Oct. 2001	**NE, CT, MI, SD, SEARHC**
	August 2002	**VT**
	October 2002	**IA**
	December 2003	**IL**
	March 2004	**MO**
	July 2004	**WV**

SECTION 1: NUMBER OF WOMEN AND SCREENINGS

Number of	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec	Total	CDC Minimum Standard per year*
Total Screenings	19,765	16,685	21,057	57,507	2,500
New Women Screened	15,126	12,954	12,924	41,004	.
Range for new screens (Project's min & max)	19-6,121	7-4,131	29-3,115	29-9,269	

Comments: The number of Total Screenings refers to the total number of cardiovascular risk factor screenings that have taken place. This number may include baseline screening and annual re-screening. The number of New Women Screened refers to the number of women who have been screened through WISEWOMAN for cardiovascular disease (CVD) risk factors for the first time. At a minimum, participants are screened to determine if they have abnormal BMI, blood pressure, and cholesterol. Each woman is also asked health behavior questions to learn more about her diet, physical activity, and tobacco use.

*The minimum number of women that a project is to screen is determined by the type of project (standard or enhanced) and the funding level (level one or level two per Appendix B in Program Announcement 03022). The minimum number of women screened for enhanced (intervention research) projects is individualized and based on power calculations. Standard projects that receive level one funding are to screen a minimum of 500 women each year. Standard projects that receive level two funding are to screen a minimum of 2500 women each year.

SECTION 2: EVALUATION (First Annual) SCREENING VISIT

Annual Re-Screens

Baseline Period	Re-Screened at 10-14 months	Re-Screened at 15-18 months	Re-Screened at 19-24 months	Re-Screened at >24 months
Jan-Dec 03	31% (4013/ 12930)	6% (713/ 12930)	1% (86/ 12930)	0% (0/ 12930)
Jan-Dec 02	28% (1790/ 6435)	8% (516/ 6435)	5% (346/ 6435)	4% (237/ 6435)
Jan-Dec 01	27% (744/ 2777)	7% (208/ 2777)	6% (161/ 2777)	8% (223/ 2777)
Jan-Dec 00	24% (489/ 2028)	6% (119/ 2028)	4% (81/ 2028)	6% (130/ 2028)
prior to Jan 00	37% (947/ 2583)	7% (168/ 2583)	4% (107/ 2583)	9% (244/ 2583)
CDC Standard	75%			

Comments: % refers to the percent of women re-screened in the specified time period, the numerator is the number of women re-screened in the specified time period, the denominator is the total number of women screened during baseline period.

CVD screening results are collected each year to help determine if the WISEWOMAN program is effective. Although national guidelines may indicate that a woman with a normal value does not need to be re-screened one year later (national clinical guidelines recommend that people with normal blood pressure return in 2 years; normal cholesterol, 5 years; normal glucose, 3 years), the WISEWOMAN program requires annual screening to facilitate program evaluation. A minimum of 75% of all women initially screened will return for one annual re-screen per CDC performance indicator standard.

SECTION 3: INTERVENTION ATTENDANCE

Intervention Session Attendance

Number of Intervention Sessions	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec	CDC Standard
0	26% (3920/14854)	41% (5047/12277)	45% (5546/12198)	
>=1	74% (10934/14854)	59% (7230/12277)	55% (6652/12198)	75%
Complete	43% (6330/14854)	33% (4099/12277)	28% (3367/12198)	60%

Comments: % refers to the percent of women with a baseline visit attending specified number of intervention sessions or completing a core set of interventions; the numerator is the number of women attending specified number of intervention sessions or completing a core set of interventions, the denominator is the total number of women with a baseline visit. For enhanced projects, the number of women in the denominator is the total number of women with a baseline visit assigned to an intervention group.

Health promoting lifestyle interventions have been designed to provide WISEWOMAN participants with the knowledge, skills, and opportunities needed to improve diet, physical activity, and other life habits (like tobacco

cessation counseling) to prevent, delay, or control CVD and other chronic diseases. To meet the CDC performance standard, 75% of women who have received CVD risk factor screening must attend at least one intervention session, and 60% must complete all intervention sessions.

SECTION 4: AGE PROFILE

Age Category	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec
Age<30		0% (2/12954)	0% (6/12924)
Age 30-39	1% (182/15126)	3% (440/12954)	4% (504/12924)
Age 40-49	35% (5255/15126)	45% (5865/12954)	47% (6046/12924)
Age 50-64	62% (9428/15126)	51% (6626/12954)	49% (6342/12924)
Age>=65	2% (261/15126)	0% (21/12954)	0% (26/12924)

Comments: % refers to the percent of women with a baseline visit in the specified age category, the numerator is the number of women in the specified age category, the denominator is the total number of women with a baseline visit.

WISEWOMAN services are provided to 40- to 64-year-old women who are enrolled in the state or tribal organization's BCCEDP.

The WISEWOMAN Program has granted special permission to two projects (SD and SEARHC), which allows them to provide WISEWOMAN screening and intervention to women aged 30-64 years.

SECTION 5: BASELINE RISK PROFILE

Risk Factor	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec
a) Pre-Hypertension (120/80-139/89)	33% (4683/14403)	35% (4320/12512)	34% (4240/12570)
b) Hypertension (>=140/90 or meds)	42% (6031/14403)	36% (4474/12512)	35% (4337/12570)
c) Borderline High Cholesterol (200-239)	35% (4941/14232)	33% (4056/12458)	32% (4041/12557)
d) High Cholesterol (>=240 or meds)	30% (4312/14232)	27% (3382/12458)	27% (3380/12557)
e) Pre-Diabetes (BG 100-125)*	14% (1226/ 9064)	16% (1326/ 8213)	15% (1145/ 7767)
f) Diabetes (BG>=126 or history or meds)	10% (871/ 9064)	10% (827/ 8213)	10% (805/ 7767)
g) Smoking	25% (3649/14713)	26% (3404/12906)	28% (3629/12855)
h) Overweight (BMI 25-29.9)	30% (4259/14060)	30% (3604/12013)	29% (3501/12141)
i) Obese (BMI>=30)	43% (6022/14060)	45% (5351/12013)	45% (5430/12141)
j) None of the Above	6% (834/15126)	5% (710/12954)	6% (753/12924)

Comments: % refers to the percent of women at baseline with a risk factor, the numerator is the number of women at baseline with a risk factor, the denominator is the total number of women at baseline with non-missing lab data.

*Pre-Diabetes is defined as a fasting blood glucose 100-125mg/dl or a non-fasting glucose 140-199 mg/dl. Diabetes is defined as a fasting blood glucose>=126mg/dl or a non-fasting glucose >=200 mg/dl or history of diabetes or taking medication for diabetes.

SECTION 6: NEWLY DETECTED CASES

Risk Factor	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec
Hypertension	29% (1726/6031)	28% (1249/4474)	27% (1165/4337)
High Cholesterol	45% (1929/4312)	42% (1429/3382)	40% (1361/3380)
Diabetes	24% (209/ 871)	25% (208/ 827)	26% (209/ 805)

Comments: % newly detected refers to the percent of women with a risk factor at baseline who state that they do not take medications for this condition, nor have they been told previously that they have this condition. The numerator is the number of women who state that they do not take medications for a specified condition, nor have they been told previously that they have this condition. The denominator is the total number of women at baseline with an abnormal reading for a specified measurement.

SECTION 7: CHANGES IN CHD/CVD RISK

Research Sites:

Predicted Risk	Statistic	Control Group				Intervention Group			
		Baseline Period:							
		Jan 00 - Dec 01	Jan-Dec 02	Jan-Dec 03	All periods	Jan 00 - Dec 01	Jan-Dec 02	Jan-Dec 03	All periods
10yr CHD risk, Anderson	Baseline	3.8	5.8	6	5.9	5.3	5.3	6.1	5.9
	1yr Follow-Up	3.8	5	5.7	5.5	5.5	4.5	5.6	5.4
	% Change	-1.5	-13.5*	-5.4*	-6.9*	3.1	-16*	-8.3*	-9.2*
	N	17	96	345	458	22	83	265	370
5yr CVD risk, Jackson	Baseline	2.6	3.1	3.8	3.6	3.9	3.3	3.7	3.6
	1yr Follow-Up	2.8	3	3.5	3.4	3.5	2.5	3.5	3.3
	% Change	5.6	-2.5	-6.9*	-5.7*	-8.8	-22.9*#	-5.7	-9.4*
	N	17	96	345	458	22	83	265	370

*indicates statistically significant changes from zero ($p<0.05$)
#indicates statistically significant differences between control and intervention groups ($p<0.05$)

Standard Sites:

		Baseline Period:				
Predicted Risk	**Statistic**	**prior to Jan 00**	**Jan 00 -Dec 01**	**Jan-Dec 02**	**Jan-Dec 03**	**All periods**
10yr CHD risk, Anderson	Baseline	8.8	6.8	6.0	5.7	6.4
	1yr Follow-Up	7.9	6.6	5.5	5.4	5.9
	% Change	-11.0*	-3.6	-8.5*	-5.1*	-6.7*
	N	870	965	1331	2981	6147
5yr CVD risk, Jackson	Baseline	5.5	4.3	3.5	3.3	3.8
	1yr Follow-Up	4.8	3.9	3.2	3.0	3.4
	% Change	-12.5*	-9.0*	-8.3*	-7.9*	-9.1*
	N	870	965	1331	2981	6147

*indicates statistically significant changes from zero ($p<0.05$)

Comments: N refers to the number of women with a baseline screening in the specified time period who have completed 1-year followup and have non-missing data for all elements required to calculate the risk score.

Anderson's calculator estimates a 10-year probability of developing a coronary heart disease (CHD). Jackson's calculator estimates a 5-year probability of developing cardiovascular disease (which includes CHD and stroke, heart failure, and peripheral vascular disease). Both calculators use sex, age, systolic blood pressure, total cholesterol, high-density lipoprotein cholesterol, smoking, and diabetes status as input risk factors. Jackson's calculator also accounts for diastolic blood pressure.

Sources:

1. Anderson KM, Wilson PW, Odell PM, Kannel WB. An updated coronary risk profile. A statement for health professionals. *Circulation* 1991 Jan;83(1):356-362.

2. Jackson R. Updated New Zealand cardiovascular disease risk-benefit prediction guide. *BMJ* 2000;320(7236):709-710.

SECTION 8: CHANGES IN CVD RISK FACTORS

Research Sites:
Percent Change from Baseline to Follow-Up

Factor	Control Group				Intervention Group			
	Baseline Period:							
	Jan00 -Dec 01	Jan-Dec 02	Jan-Dec 03	All periods	Jan00 - Dec 01	Jan-Dec 02	Jan-Dec 03	All periods
SBP	-6.4*	-0.9	-1.1	-1.4*	-4.9*	-1	-0.5	-1
DBP	-2.7	-0.3	-1.5*	-1.3*	0.9	-1.8	0.3	-0.1
TC	0.4	-4.5*	-2.6*	-2.8*	0.5	0.4	-3.3*	-2.2*
BG	8.8*	1.2	2.3	2.6	5.5*	6.6*	-2.1	1.9
Weight	-0.2	0.2	0.1	0.1	-1.9	-0.1	-0.9*	-0.9*
Smoking	0	0	-3.8	-2.8	0	-15.6	6.5	-1

*indicates statistically significant changes from zero ($p<0.05$)
#indicates statistically significant differences between control and intervention groups ($p<0.05$)

Standard Sites:
Percent Change from Baseline to Follow-Up

Factor	Baseline Period:				
	prior to Jan 00	Jan00-Dec01	Jan-Dec 02	Jan-Dec 03	All periods
SBP	-1.9*	-1.2*	-0.6*	-0.9*	-1*
DBP	-1.5*	-1.6*	-1.5*	-0.8*	-1.2*
TC	-1.5*	-2.8*	-1.2*	-1.8*	-1.8*
BG	.	0.5	0.2	0.5	0.4
Weight	0.6*	-0.3	0	0	0
Smoking	-15.3*	-12.1*	-10.8*	-5.7*	-9.1*

*indicates statistically significant changes from zero ($p<0.05$)
#indicates statistically significant differences between control and intervention groups ($p<0.05$)

SECTION 9: CHANGES IN PHYSICAL ACTIVITY AND NUTRITION VARIABLES

n/a

SECTION 10: ALERT VALUES

Period	Risk Factor	N with Alert	% Referred (N)	Mean Days From Screen to Referral (range)	% Seen (N)	Mean Days From Screen to Seen (range)	% Already on Meds (N)	% Prescribed Meds (N)
1). Year 2004 (Jan-Dec)	Blood Pressure (>180/110)	97	68% (66)	2(0, 33)	82% (54)	8(0, 87)	57% (31)	31% (17)
	Glucose (>375)	9	78% (7)	0(0, 2)	86% (6)	5(0, 22)	67% (4)	17% (1)
	Total Cholesterol (>400)	19	79% (15)	5(0, 29)	93% (14)	32(0, 136)	7% (1)	57% (8)
2). Year 2003 (Jan-Dec)	Blood Pressure (>180/110)	114	70% (80)	1(0, 56)	94% (75)	11(0, 134)	52% (39)	41% (31)
	Glucose (>375)	14	79% (11)	1(0, 5)	100% (11)	0(0, 2)	36% (4)	45% (5)
	Total Cholesterol (>400)	16	69% (11)	9(0, 49)	91% (10)	9(-13, 50)	0% (0)	50% (5)
3). Historical (prior to Jan'03)	Blood Pressure (>180/110)	187	45% (85)	0(0, 11)	94% (80)	20(0, 428)	58% (46)	35% (28)
	Glucose (>375)	30	43% (13)	2(-4, 9)	77% (10)	15(0, 92)	50% (5)	20% (2)
	Total Cholesterol (>400)	24	63% (15)	4(0, 27)	87% (13)	15(0, 51)	23% (3)	31% (4)
4). CDC Standard		.			95% (w/in 1 wk)			

Comments: % referred is out of those with an alert value, % seen is out of those referred, and % already prescribed med and % prescribed meds is out of those seen. All women who have an alert screening value will be evaluated immediately or within one week. The percent of women with an alert screening value who fail to follow through with the health care provider immediately or within one week will be no more than 5 percent.

SECTION 11: MISSING SECOND BLOOD PRESSURES

Error	Historical: Jan98 - Dec02	Year 2003: Jan-Dec	Year 2004: Jan-Dec
% Missing	0% (0/18862)	0% (0/16052)	0% (16/20438)
% 777 (refused)	0% (16/18862)	0% (43/16052)	0% (62/20438)
% 888 (unable to obtain)	0% (22/18862)	3% (428/16052)	3% (645/20438)
% 999 (not tested)	60% (11308/18862)	18% (2854/16052)	14% (2935/20438)
All of the Above	60% (11346/18862)	21% (3325/16052)	18% (3658/20438)

Comments: % refers to the percent of records with a specified error. The numerator is the number of records with a specified error. The denominator is the number of total records in the specified time period.

Appendix K

Literature Reviews

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Health Promotion Interventions for Disadvantaged Women: Overview of the WISEWOMAN Projects

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ABSTRACT

Background: **The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program aims to remove racial and ethnic disparities in health by addressing the screening and intervention needs of midlife uninsured women. This paper describes the WISEWOMAN program requirements, the design of the 12 projects funded in 2002, the use of a standardized data reporting and analysis system, risk factors among participants, effective behavioral strategies, and plans for the future.**

Methods: **The WISEWOMAN demonstration projects are examining the feasibility and effectiveness of adding a cardiovascular disease (CVD) prevention component to the early detection of breast and cervical cancer. Women aged 40–64 are eligible if they are enrolled in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in selected U.S. states and are financially disadvantaged and lack health insurance. The primary outcome measures are blood pressure, lipid levels, and tobacco use. Intermediate measures include self-reported diet and physical activity, measures of readiness for change, and barriers to behavior change.**

Results: **During 2002, the 10 projects that were fully operational screened 8164 financially disadvantaged women and developed culturally and regionally appropriate nutrition and physical activity interventions for a variety of racial and ethnic backgrounds. Twenty-three percent of the women screened had high total cholesterol, with 48% of these being newly diagnosed. Thirty-eight percent of the women had high blood pressure, with 24% being newly diagnosed. Approximately, 75% of participants were either overweight or obese, and in some sites up to 42% were smokers.**

Conclusions: **The WISEWOMAN demonstration projects have been successful at reaching financially disadvantaged and minority women who are at high risk for chronic diseases. These projects face challenges because they are generally implemented by safety net providers who have limited resources and staff to conduct research and evaluation. On the other hand, the findings from these projects will be especially informative in reducing health disparities because they are conducted in those settings where the most socially and medically vulnerable women receive care.**

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INTRODUCTION

IMAGINE A WORLD WHERE ANY WOMAN can access preventive health services and gain the wisdom to improve her health. This is the vision promoted by the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program. To achieve this vision, fundamental changes in our society's healthcare systems are needed. At present, roughly 1 in 5 working-age women lacks health insurance,[1] and minority patients, even when insured, are less likely than whites to enjoy a consistent relationship with a provider.[2] The lack of health insurance and of a usual source of care has been described by the American Society of Internal Medicine (American College of Physicians) and the Institute of Medicine as a barrier to receiving important preventive care.[1,3] Ensuring access to preventive health services, therefore, requires expanding healthcare coverage and ensuring consistent and trusting relationships between providers and patients. However, research on racial and ethnic disparities in healthcare indicates that even after accounting for insurance and income, some social groups still receive unequal treatment.[3] The reasons for these disparities are complex and may be occupational, cultural, or linguistic. Thus, preventive healthcare strategies that are sensitive to the economic and cultural context of women's lives are also needed.

The WISEWOMAN program was authorized by Congress in 1993 and funded in 1995. Because they recognized an opportunity to increase the provision of preventive health services to financially disadvantaged and uninsured women, the U.S. Congress asked the Centers for Disease Control and Prevention (CDC) to develop and evaluate the provision of cardiovascular disease (CVD) and other prevention services to women who were already attending the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). In response to this request, CDC invited state and territorial departments of health and tribal agencies to design creative strategies to add CVD screening and lifestyle interventions to their breast and cervical cancer screening programs.

During Phase One of the WISEWOMAN program (1995–1998) (Fig. 1), awards were given to three state health departments (North Carolina, Massachusetts, and Arizona) to conduct "enhanced" projects (i.e., projects involving research with control groups, described in detail later). Phase Two began in 1999, when Congress authorized expansion of the WISEWOMAN program, and monies were awarded for "standard" projects (i.e., projects that test feasibility without the use of control groups) as well as enhanced projects. As a result of the expanded competition, 12 state and tribal health agencies now operate WISEWOMAN projects (Fig. 2).

Published results from the first phase of WISEWOMAN indicated that it is appropriate but sometimes challenging to expand breast and cervical cancer early detection programs (BCCEDP) to include screening and interventions to lower CVD risk factors.[4,5] Results showed that WISEWOMAN interventions can increase physical activity and improve nutrition.[6–8] In all three programs, although differences by intervention groups were not apparent, participants appeared to have improvements in some biological risk factors after 1 year. In North Carolina, the average drop in cholesterol was 7–8 mg/dl. Because both intervention groups experienced the same drop in cholesterol, the improvement could not be attributed to the more intensive intervention.[9] In Massachusetts and Arizona, the percentage of women with high blood pressure also dropped for all groups between baseline and 1-year follow-up.[6,7] Challenges to BCCEDP expansion included healthcare providers who felt overburdened by research and newly funded BCCEDP projects that lacked the stability to add yet another set of program requirements.[5]

Important remaining questions are being addressed in the second phase of WISEWOMAN. For example, what is the burden of risk factors among the diverse populations served by WISEWOMAN? How are the WISEWOMAN projects perceived by participants and providers? Which intervention strategies are especially effective in reducing CVD risk factors and improving the ability of women to make behavioral changes? What approaches are particularly successful in influencing multiple social levels (e.g., individuals, families, and communities)? What are the costs of conducting the WISEWOMAN projects? Some of these questions are addressed in this paper, others are discussed in the papers that follow in this special supplement on the WISEWOMAN program, and some questions will be answered in the future.

In this overview, we provide information on WISEWOMAN program requirements, the design of 12 currently funded projects, the use of

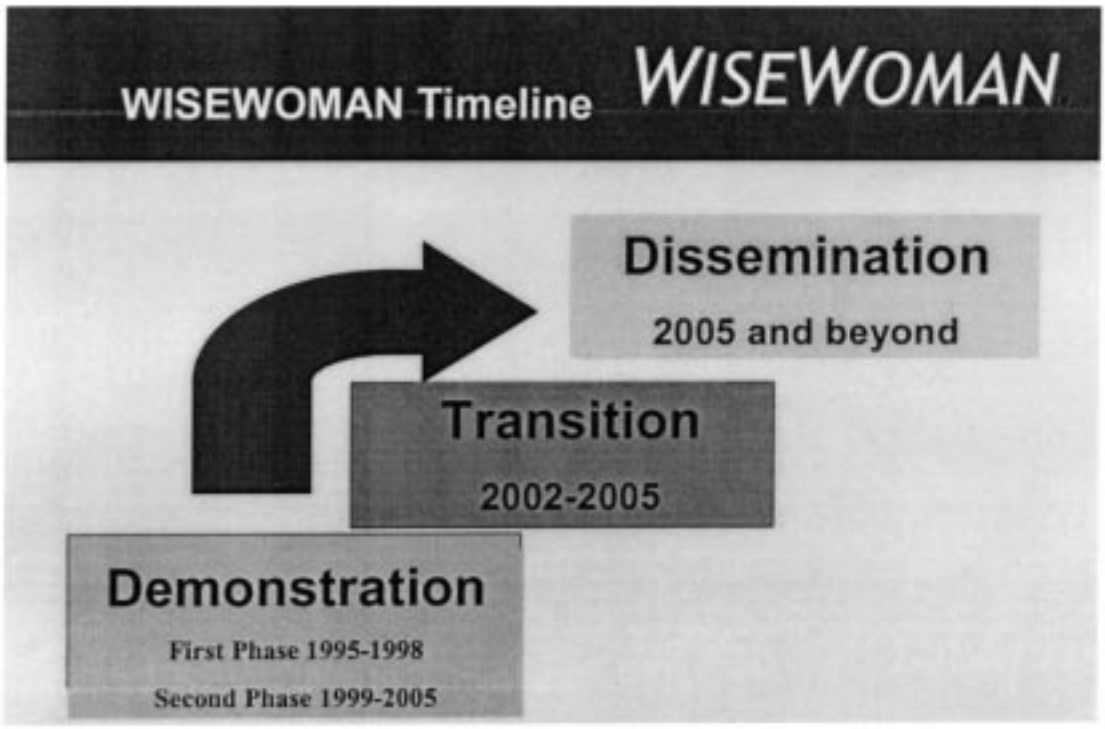

FIG. 1. The federal WISEWOMAN program: Phases and timeline.

standardized data to allow comparisons across projects, the burden of risk factors in our study populations, effective behavioral strategies, and plans for the future. Ultimately, approaches that prove feasible and cost-effective in the WISEWOMAN program will aid the public health community in combating disparities in access to preventive healthcare and improving knowledge and skills to effect behavioral change.

PROGRAM REQUIREMENTS

To fulfill the vision of the WISEWOMAN program, funds are provided for preventive health screenings, appropriate medical referrals, and lifestyle interventions to women aged 40–64 who have participated in the NBCCEDP.[10] Federal dollars are provided to CDC, which then uses at least 80% of the money to fund state and territorial health departments and tribal agencies to develop the WISEWOMAN services. CDC uses the other 20% to fund universities or private contractors to conduct additional program activities, such as evaluation and development of interventions. CDC also funds a small group of in-house staff to provide scientific and programmatic advice to recipients of WISEWOMAN funds. Thus, the federal WISEWOMAN program relies heavily on paid partners outside of CDC to fully develop the program. Currently, most of these partners are located in state health agencies. Although Congress prohibits the use of federal monies for treatment, project partners are required to develop a treatment plan when women have abnormal screening results.

Screening

The WISEWOMAN projects are required to screen for high blood pressure and high cholesterol levels and are allowed to screen for other clinical conditions, such as abnormal blood glucose and overweight or obesity. All screenings must be performed according to recommendations published in national clinical guidelines.[11–14] In many of the projects, personnel also conduct written behavioral assessments to detect tobacco use, poor dietary habits, sedentary lifestyle, or high risk of osteoporosis. In addition to paying for specified screening tests, the WISEWOMAN program provides monies for confirmation of abnormal screening results and an annual follow-up examination. Some projects are

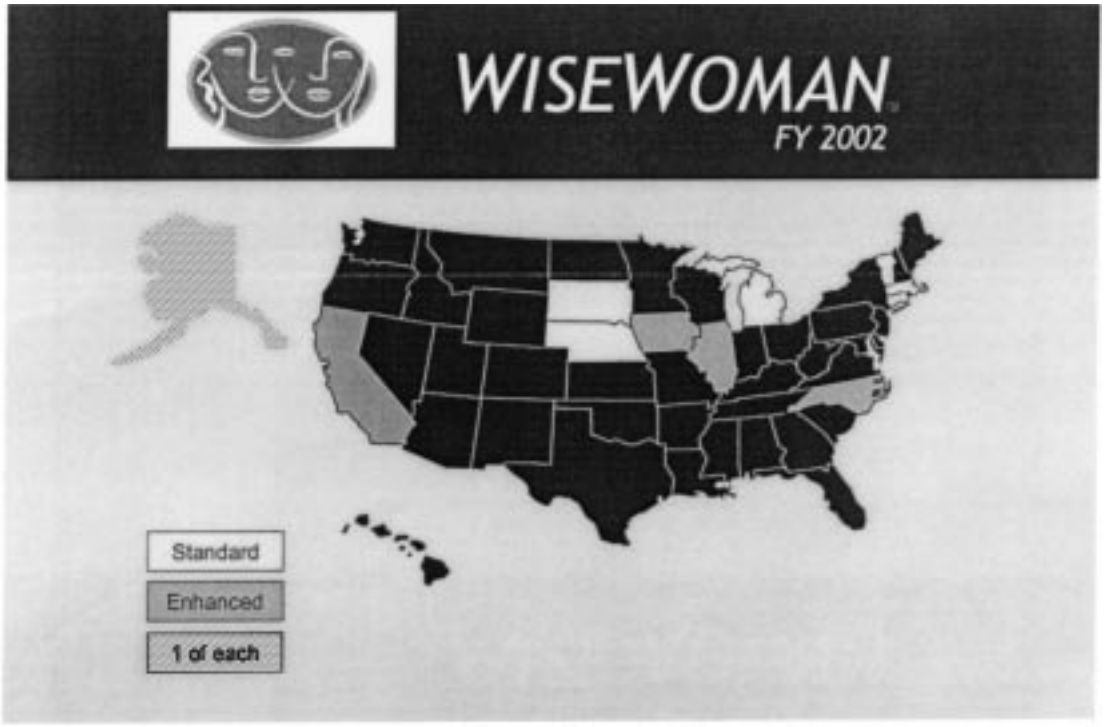

FIG. 2. Locations of WISEWOMAN projects funded in 2002.

allowed to pay for a 6-month visit to collect needed data for research purposes.

Medical referral

All WISEWOMAN participants who have high blood pressure, high cholesterol, or high blood glucose according to national guidelines will require further medical attention. At a minimum, the WISEWOMAN projects must ensure that women are referred for a diagnostic examination to confirm screening results. Staff are urged to send a medical referral form along with a letter that describes the intervention and the participant's clinical results. The referral form often will state the reasons for the referral and include the clinician's initial assessment and recommendations. To help track referrals, the WISEWOMAN program strongly recommends that clinicians keep a copy of the form and send the original back to the referring agency. At all projects, the staff are responsible for documenting that a referral was made.

Lifestyle interventions

According to national clinical guidelines, the first step toward improving abnormal clinical values is usually the provision of lifestyle interventions. WISEWOMAN project staff develops lifestyle interventions targeted toward the population served, that is, multiethnic, financially disadvantaged women. Staff are required to review the existing literature and select scientifically sound, culturally relevant interventions that will be most effective for their populations. Thus, lifestyle interventions vary across projects.

Evaluation

WISEWOMAN projects include an evaluation or research component. Project staff must report 23 standardized data elements beyond what is already required by the NBCCEDP. These minimum data elements (MDEs) are reported to the Research Triangle Institute (RTI) twice a year. In addition, the project staff is expected to design physical activity and nutrition assessments that measure the effects of the intervention. For example, if the intervention staff encourages women to walk more each day, they may assess walking time as a measure of success. The assessments are not standardized across projects but must be reported to RTI. Projects may collect as much additional information as they wish.

For all projects, the primary outcome measures

are blood pressure and lipid levels. Intermediate measures include self-reported diet and physical activity, measures of readiness for change, and barriers to behavior change, which are assessed as modifiers of the intervention effect.

PROJECT DESIGN

Enhanced projects

Enhanced projects are designed to determine the most effective lifestyle interventions for underserved women by comparing women who receive an enhanced intervention with women who receive a minimum intervention or usual care. Assignment to the minimum or enhanced intervention is either by group (clinic or county) or by woman; for both designs, the unit of observation is the individual woman. All enhanced projects report MDEs to RTI but also collect additional information to support further analyses. The group-randomized design effect is accounted for statistically in all analyses.[15]

Although details of the minimum intervention vary by project, all enrolled women receive baseline screening for CVD risk factors and minimal on-site counseling, education, referral, and follow-up using established protocols.[11–14] Repeat screening is recommended at 6 and 12 months after the initial screening. Women enrolled in the enhanced intervention receive all services of the minimum intervention plus a specially designed education and intervention program tailored to the population served. Some projects have employed a third intervention group that is even more intensive and may include services such as those provided by community health workers.

In 2002, five WISEWOMAN enhanced projects operated in selected breast and cervical cancer screening sites in California, North Carolina, Illinois, Iowa, and the Southcentral Foundation in Alaska (Table 1). As in Phase One, these enhanced projects continue to conduct research to determine whether the enhanced intervention has a greater impact on risk factors than the minimum intervention. All five projects have developed intervention strategies tailored to participants' racial and ethnic profile and age group (40–64 years).

Standard projects

Standard projects are designed to determine the best operational methods for delivering CVD screening and evidence-based lifestyle interventions to eligible uninsured women. Standard projects are similar to the enhanced intervention component of enhanced projects because they provide services that improve upon the usual care at each clinic. However, standard projects do not employ an experimental design with a control group. Participants in standard projects receive baseline screening for CVD risk factors, on-site counseling, education, referral, and follow-up, with repeat screening at 12 months. All activities are based on established protocols.[11–14] In addition, standard projects offer a specially designed education and intervention program tailored to the population served. All projects report MDEs to RTI. In 2002, the seven funded standard projects operated in selected breast and cervical cancer screening sites in Connecticut, Massachusetts, Michigan, Nebraska, South Dakota, the Southeast Alaska Regional Health Consortium (SEARHC), and Vermont (Table 2).

RISK FACTOR BURDEN

In 2002, the 10 projects that were fully operational screened 8164 financially disadvantaged women (Tables 3 and 4). Women have been screened from a variety of racial/ethnic groups. North Carolina, Connecticut, and Michigan have screened high proportions of African Americans (39%, 28%, and 17%, respectively), and Connecticut, Massachusetts, and Nebraska have been effective in reaching Hispanic/Latina women (25%, 28%, and 11%, respectively). All of the women screened by Alaska's Southcentral Foundation have been Alaska Natives. The WISEWOMAN projects, therefore, are effective in reaching minority women.

Data on various chronic disease risk factors are available for some Phase Two WISEWOMAN projects for 2002 (Tables 3 and 4). In all states, substantial proportions of women screened (17%–37%) had high total cholesterol. However, many were unaware of their cholesterol status, ranging from 24% at SEARHC to 60% in Massachusetts and South Dakota. Approximately half (40%–55%) of participants in North Carolina, Iowa, Alaska's Southcentral Foundation, Connecticut, Michigan, and Nebraska were not aware of having high cholesterol. Women in North Carolina showed the highest prevalence of hyper-

TABLE 1. SELECTED FEATURES OF THE ENHANCED WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	California	*North Carolina*	*Illinois*	*Iowa*	*Southcentral Foundation*
Year first funded	2001	1995	2001	2000	1999
Lead agency	California Department of Health Services	North Carolina Department of Health and Human Services	Illinois Department of Public Health	Iowa Department of Public Health	Alaska Native Medical Center
Key partners	University of California at Davis, University of California at San Francisco, American Heart Association Western States Affiliate (CA chapter), American Cancer Society (CA chapter)	University of North Carolina Schools of Public Health and Medicine	University of Illinois at Chicago, The Cooper Institute	University of Iowa at Iowa City, Iowa State University Extension Services at Ames	University of North Carolina at Chapel Hill, "Take Heart Alaska" CVD prevention program, Alaska Primary Care Association's Statewide Women's Health Partnership, Alaska Dietetic Association, Alaska Area Diabetes Program
WISEWOMAN sites (number and type)	5 pilot sites have been selected; full-scale study sites to be selected later	39 local health departments serving 40 of 100 North Carolina counties; one community health center serves as research site	3 county health departments and 1 hospital that comprise 20 sites and represent suburban and rural counties	15 sites including health departments, hospitals, visiting nurse associations, home health agencies, and women's services agencies	1 family medicine clinic involving 23 physicians at Southcentral Foundation serving Anchorage Bowl area
Site selection and method of assignment to interventions[b,c]	Participants at pilot sites randomly assigned to EI or MI	Counties selected based on ability of BCCEDP site to meet screening goals; all health department sites receive EI; at community health center (selected based on BCCEDP participation and willingness to implement research design), women randomized to EI or MI	Counties selected based on strong BCCEDP performance and infrastructure, and to achieve geographic mix; women in each site randomized to EI or MI	Counties selected based on strong BCCEDP performance, and randomly assigned to EI or MI	Participants randomly assigned to EI or MI; the EI is offered to the MI group after 1 year

(continued)

TABLE 1. (CONT.) SELECTED FEATURES OF THE ENHANCED WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	California	*North Carolina*	*Illinois*	*Iowa*	*Southcentral Foundation*
Participant eligibility for intervention	Latina BCCEDP participants aged 40–64 who are screened with high serum cholesterol or elevated systolic or diastolic blood pressure, or who are taking medications for such conditions at the time of screening	BCCEDP participants aged 40–64 who are screened with high serum cholesterol or other abnormal lipids, elevated systolic or diastolic blood pressure or abnormal glucose, or a personal history of these conditions	All recruited BCCEDP participants aged 40–64	All recruited BCCEDP participants aged 40–64	All recruited BCCEDP participants aged 40–64 residing within 50 miles of primary care center
Participant recruitment strategies[c,d]	Free CVD screening offered when Latina BCCEDP clients come to clinic for breast and cervical examination; also conduct community outreach and mailings	Free CVD screening offered when BCCEDP clients come to clinic for breast and cervical examination	Free CVD screening offered when BCCEDP clients come to clinic for breast and cervical examination; also use fliers, personalized phone calls, and recruitment festivals	Free CVD screening offered when BCCEDP clients come to clinic for breast and cervical examination; fliers that are mailed as reminders for BCCEDP repeat screenings include an announcement regarding CVD services	Recruited at Southcentral Foundation through the BCCEDP and family medicine providers; also use letters and phone calls to eligible women and community advertising (e.g., posters, public service announcements, presentations)
Intervention participation rate	Data not yet available	89% of health department participants received at least one lifestyle intervention; data not yet available for community health center research site	Data not yet available	Data not yet available	78% of women randomized to the intervention attended at least 1 session; 65% attended at least 6 of 12 sessions
Features of baseline screenings and risk factor assessments[e]	Hypertension, hypercholesterolemia, overweight, personal and family medical history, cigarette smoking, poor diet, physical inactivity	Hypertension, hypercholesterolemia, other abnormal lipids, abnormal glucose values, overweight, personal and family medical history, cigarette smoking, poor diet, physical inactivity; research site includes the above plus red	Hypertension, hypercholesterolemia, high triglycerides, abnormal glucose values, abnormal pulse, overweight, abdominal obesity, personal and family medical history, cigarette smoking, poor diet, physical inactivity	Hypertension, hypercholesterolemia, overweight, personal and family medical history, cigarette smoking, poor diet, physical inactivity	Hypertension, hypercholesterolemia, high triglycerides, other abnormal lipids, abnormal glucose values, overweight, abdominal obesity, abnormal electrocardiogram, abnormal kidney function, abnormal thyroid

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	blood cell membrane fatty acid profiles and blood carotenoids				function, personal and family medical history, tobacco use, poor diet, physical inactivity
Features of MI	CVD risk factor screening, diagnosis, and referral according to national clinical guidelines, and health education based on usual care offered at clinical site using an educational pamphlet (e.g., American Heart Association)	All health department sites receive EI; the research site's MI consists of CVD risk factor screening, diagnosis, and referral according to national clinical guidelines, and health education using an educational pamphlet (e.g., American Heart Association)	CVD risk factor screening, diagnosis, and referral according to national clinical guidelines, and health education using an educational pamphlet (e.g., American Heart Association; National Heart, Lung, and Blood Institute)	CVD risk factor screening, diagnosis, and referral according to national clinical guidelines, and health education using educational pamphlets preselected by state project staff	CVD risk factor screening, diagnosis, and referral according to Southcentral Foundation's clinical guidelines; all patients are eligible for health education materials and counseling services, provided on request or per physician orders
Features of EI (nutrition and physical activity) and theoretical foundations	More frequent clinical measurements, plus *A New Leaf . . . Choices for Healthy Living*[8] or the Spanish version *(¡Vida Saludable, Corazón Contento!)*; counseling facilitated by bilinguial community health workers Through the use of social cognitive theory and the socioecological model, inervention emphasizes individual tailoring, self-efficacy, self-monitoring, readiness to change, small achievable steps, social support, collaborative goal-setting, and overcoming barriers	Same clinical services, plus *A New Leaf . . . Choices for Healthy Living*[8]; in the community health center site, women also receive follow-up phone calls and reminders from community health workers, and referrals to community resources Through the use of social cognitive theory and the socioecological model, intervention emphasizes individual tailoring, goa lsetting, social support, and identification of barriers and perceived benefits	Same clinical services, plus a 12-week nutrition and physical activity group intervention called *Women with Heart* (based on *Project Active*[16]); (a Spanish version, *Mujeres con Corazón*, is being developed); sessions with health educators focus on portion sizes, food labels, stress management, and moderate physical activity Intervention is designed to remove barriers, increase social support, and improve self-efficacy	A 12-session group format led by Cooperative Extension nutritionists; each session includes a healthy snack, topic presentation, brief physical activity, skill-building activity, behavior change/ maintenance activity, goal-setting activity, and evaluation; nutrition topics are based on the DASH[f] diet[17] Intervention is designed to remove barriers, increase social support, and improve self-efficacy	A 12-session group covering traditional wellness, nutrition, physical activity and tobacco education topics, team-taught by nutritionists, exercise physiologists, and health educators; includes *Traditions of the Heart*, a cultural adaptation for Alaska Natives of *A New Leaf . . . Choices for Healthy Living*[8]; includes structured diet and physical activity assessments, individual counseling, and tailored goal-setting by health educators Intervention addresses social support and barriers to change

(continued)

TABLE 1. (CONT.) SELECTED FEATURES OF THE ENHANCED WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	California	*North Carolina*	*Illinois*	*Iowa*	*Southcentral Foundation*
Features of EI (tobacco control)	Smoking cessation module from *New Leaf* (and Spanish version) used to provide cessation tips, plus referral to community agency	Smoking cessation module from *New Leaf* used to provide cessation tips, plus referral to community agency or local smoking cessation resources	Referral to tobacco cessation program if participant expresses desire to quit	Referral to smoking cessation program for participants with self-disclosed smoking behavior; reimbursement given to provider who delivers smoking cessation program	Using *Traditions of the Heart*, participants complete tobacco use assessment (cigarette smoking and tobacco chewing), receive individual counseling, and set goals to stop using tobacco; each intervention session covers risks associated with tobacco use and benefits of quitting; tobacco users also referred to tobacco clinic for counseling, quit aids, and other services
Main outcomes	Hypertension and hypercholesterolemia	Hypertension and hypercholesterolemia	Hypertension and hypercholesterolemia	Hypertension, hypercholesterolemia, and obesity	Hypertension and hypercholesterolemia
Comparability between intervention groups at baseline	Data not yet available	Data not yet available for research site	Data not yet available	Data not yet available	Data not yet available for full-scale study

[a]Well-Integrated Screening and Evaluation for Women Across the Nation.
[b]EI, enhanced intervention; MI, minimum intervention.
[c]BCCEDP, Breast and Cervical Cancer Early Detection Program.
[d]CVD, cardiovascular disease.
[e]Some baseline screenings are paid for by WISEWOMAN and others by matching funds.
[f]DASH, Dietary Approaches to Stop Hypertension.

TABLE 2. SELECTED FEATURES OF THE STANDARD WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	Connecticut	*Massachusetts*	*Michigan*	*Nebraska*	*South Dakota*	*SEARHC*[b]	*Vermont*
Year first funded	2000	1995	2000	2000	2000	2000	2000
Lead agency	Connecticut Department of Public Health	Massachusetts Department of Public Health	Michigan Department of Public Health	Nebraska Department of Public Health	South Dakota Department of Public Health	SEARHC Community Health Services Division	Vermont Department of Public Health
Key partners	Connecticut Chapter of American Heart Association, Yale Prevention Research Center, InfoLine (tobacco cessation)	New England Coalition for Health Promotion and Disease Prevention, American Heart Association, regional outreach contractors, YWCA, Visiting Nurse Association	Michigan Public Health Institute, healthcare providers, federally qualified health centers, local health departments	University of Nebraska Medical Centers, College of Pharmacy, American Heart Association, Cooperative Extension, parish nurses, tribal organizations, outreach workers	Indian Health Service, pharmaceutical companies, Avera-McKennan Cardiac Rehabilitation and Prevention Program, Wellmark Blue Cross Blue Shield of South Dakota, American Cancer Society	University of Alaska at Sitka, *Take Heart Alaska* CVD prevention program, public health nurses, Alaska Tobacco Control Alliance	Primary Care Association, American Heart Association, Cardiovascular Disease Coalition, Area Health Education Center, Commuity Health Center, Richford Health Center, Northern Counties Health Care, Vermont Coalition of Clinics for the Uninsured
BCCEDP sites (number and type)[d]	18 sites, including hospitals, a federally funded community health center, and Planned Parenthood	34 Massachusetts Women's Health Network medical provider sites	21 agencies with subcontracted providers, including 20 local health departments and the Karmanos Cancer Institute	More than 600 clinic sites form a network of providers, including federally funded community health centers, family practice agencies, county health departments, and universities	735 providers at 228 sites, including private clinics, hospital-associated health systems, Indian Health Service clinics, and federally funded community health centers	12 sites total: 8 provide breast and cervical cancer services to Alaska Natives; 2 additional sites provide cervical cancer services only to Alaskan Natives; 2 clinics provide	Approximately 800 providers at more than 250 sites, including private providers, hospitals, and community health centers

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TABLE 2. (CONT'D) SELECTED FEATURES OF THE STANDARD WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	Connecticut	*Massachusetts*	*Michigan*	*Nebraska*	*South Dakota*	*SEARCH*[b]	*Vermont*
						comprehensive services to non-native clients	
WISEWOMAN sites (number and type)	9 sites, including hospitals and a federally funded community center	10 sites, including federally funded community health centers, hospitals, clinics, private indivi-ual and group practices, clinics, and visiting nurse associations	7 sites, including local health departments, private health care providers, and federally funded community health centers	All BCCEDP sites (>600)	More than 70 BCCEDP sites	7 comprehensive sites and one cervical cancer screening site	6 pilot sites (mainly federally funded community health centers)
Participant eligibility for WISEWOMAN	BCCEDP women aged 50–64 at or below 200% of poverty level with no health insurance	BCCEDP women aged 40–64 who meet financial eligibility; recruited for BCCEDP and WISEWOMAN at the same time	BCCEDP women aged 40–64 at 250% of poverty level, under- or uninsured and without Medi-care Part B or Managed Care Medicaid	BCCEDP women aged 40–64	BCCEDP women aged 30–64; the age criterion has been lowered for demon-stration purposes	BCCEDP women aged 40–64 (Native or non-Native depend-ing on the site, but 90% are Alaska Native or American Indian)	BCCEDP women aged 40–64
Participant eligibility for intervention	Women with abnormal blood pressure or cholesterol or who use tobacco	Women with abnormal blood pressure or cholesterol, and other CVD risk factors	Women with normal screen-ing results receive basic information, and are offered one face-to-face lifestyle contact; women with abnormal results receive full intervention	All women regardless of screening results	Preference given to women with abnormal screening results; women with normal values can self-refer to intervention	All women regardless of screening results	All women regardless of screening results
Participant recruitment strategies	Outreach workers, community presentations, mailouts; also recruit when women return	Advertised via media, posters, fliers, presentations	Outreach workers, fliers, information sheets	Identified through BCCEDP database, letters sent to invite partici-pation; outreach	Identified through BCCEDP data-base; letters sent to invite participation	Identified through BCCEDP data-base, letters sent or phone calls made to invite participation	Letters sent to women 40–64 years at the community health centers; women call

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	for annual BCCEDP examination			workers used for hard-to-reach women			toll-free number to determine eligibility
Intervention participation rate	18% completed at least 1 session, 13% completed all sessions	78% received risk reduction counseling, 38% received 1 lifestyle intervention session, 7% received 2–3 sessions	55% received at least 1 lifestyle intervention session; too early to determine percentage completing all sessions	Data not yet available	Data not yet available	100% (women receive intervention immediately after screening)	Data not yet available
Features of baseline screenings and assessments	Hypertension, abnormal lipid values, abnormal glucose values, abnormal pulse, overweight, physical inactivity, poor diet, cigarette smoking	Hypertension, abnormal lipid values, abnormal glucose values, overweight, physical inactivity, poor diet, cigarette smoking	Hypertension, abnormal lipid values, overweight, physical inactivity, poor diet, cigarette smoking, problematic personal or family health history	Hypertension, abnormal lipid values, abnormal glucose values, overweight, cigarette smoking	Hypertension, abnormal lipid values, abnormal glucose values, overweight, physical inactivity, poor diet, cigarette smoking	Hypertension, abnormal lipid values, abnormal glucose values, abnormal pulse, abnormal kidney function, overweight, abdominal obesity, physical inactivity, poor diet, cigarette smoking	Hypertension, abnormal lipid values, abnormal glucose values, overweight, abdominal obesity, physical inactivity, poor diet, cigarette smoking
Features of intervention (nutrition and physical activity)	Adaptation of *A New Leaf . . . Choices for Healthy Living*[8] for nutrition; PACE[e] program for physical activity[18]	Individual assessments, education, and lifestyle counseling using the PACE program[18]; referred to community-based individual or group interventions on nutrition and physical activity	Promotion of modified DASH[f] diet and moderate physical activity[17]; use lifestyle contracts and incentives	Cooperative Extension nutritionists use *ABC for Good Health,*[19] participants receive individually tailored nutrition and physical activity interventions, complete monthly goal assessment, and *10,000 Steps* program[20,21]	*A New Leaf . . . Choices for Healthy Living*[8] for nutrition assessment and counseling; physical activity intervention modeled after *Project Active*[16]	Patient educators provide *Traditions of the Heart* (cultural adaptation of *A New Leaf . . . Choices for Healthy Living*[8] for Native Alaskan populations) at time of screening; women also referred to group-based nutrition and physical activity interventions	Individualized counseling by nutritionists using the *New Leaf . . . Choices for Healthy Living*[8] curriculum, referral to a program called *Active Living Every Day,* and participation in the Governor's Walking Challenge

(continued)

TABLE 2. (CONT'D) SELECTED FEATURES OF THE STANDARD WISEWOMAN[a] PROJECTS: PHASE TWO (2002)

	Connecticut	*Massachusetts*	*Michigan*	*Nebraska*	*South Dakota*	*SEARCH*[b]	*Vermont*
Features of intervention (tobacco control)	Referred to Connecticut quitline	Referred to Massachusetts quitline	Provided with smoking cessation information and quit kits; may also participate in one face-to-face counseling session and receive 2 phone contacts to support cessation efforts	Cessation classes provided through state health department's health education and promotion division; women also referred to Nebraska quitline	Referred to South Dakota quitline, which includes up to 6 telephone contacts	Referred to American Lung Association's *Freedom from Smoking* program and Alaska quitline; nicotine replacement therapy available free of charge, one-on-one counseling available through patient educators; project addresses cigarette smoking and tobacco chewing	Referred to Vermont quitline (funded by American Cancer Society); women offered no-cost nicotine replacement therapy

[a]Well-Integrated Screening and Evaluation for Women Across the Nation.
[b]Southeast Alaska Regional Health Consortium.
[c]CVD, cardiovascular disease.
[d]BCCEDP, Breast and Cervical Cancer Early Detection Program.
[e]Physician Assisted Counseling and Evaluation.
[f]Dietary Approaches to Stop Hypertension.

TABLE 3. RESULTS (JANUARY 1, 2002–DECEMBER 31, 2002) FROM WISEWOMAN ENHANCED PROJECTS: PHASE TWO[a]

Variable[b]	*North Carolina*	*Iowa*	*Southcentral Foundation*[c]
Number screened	2317	36[d]	412
Age, years			
<55	51	56	75
≥55	49	44	25
Race/ethnicity			
White	51	100	0
Black	39	0	0
Hispanic/Latina	6	0	0
American Indian/Alaska Native	3	0	100
Asian	1	0	0
High total cholesterol[e]	26	37	22
Unaware of high cholesterol	42	42	44
Low HDL[f]	18	19	9
Hypertension[g]	54	42	38
Unaware of hypertension	17	27	9
History of diabetes	14	3	10
Estimated coronary heart disease deaths per 1000 women expected in 10 years[h]	24	32	14
Overweight[i]	29	42	31
Obese[j]	53	42	47
Smoker	27	42	32

[a]California and Illinois data not yet available.
[b]All data are presented as percentages, except for number screened. Because of missing responses, denominators vary; most variables had few missing responses.
[c]Located in Anchorage, Alaska.
[d]Iowa did not begin screening until October 2002.
[e]≥240 mg/dl.
[f]<40 mg/dl.
[g]Systolic ≥140 mm Hg or diastolic ≥90 mm Hg or taking medication.
[h]Based on a risk projection formula that uses smoking, systolic blood pressure, total cholesterol, and age.
[i]Body mass index = 25–29.9 kg/m^2.
[j]Body mass index ≥ 30 kg/m^2.

tension (54%) of any state, and at least one third of participants (35%–44%) were hypertensive in all but two other states. Again, many participants were unaware of their hypertension (9%–27% in enhanced projects and 15%–42% in standard projects). The combined prevalence of overweight and obesity has been extremely high in all projects, affecting nearly 3 of 4 women screened in almost all settings. In one of the Alaska projects (SEARHC), 60% of the women who attended the program in 2002 were obese (body mass index [BMI] ≥ 30 kg/m^2). In addition, several projects have reported a high prevalence of smoking during the first year of screening, including 42% in both South Dakota and Iowa. In several other projects, the prevalence of smoking (23%–33%) was higher than the prevalence of 21% for women aged 45–64 in the U.S. population.[22]

BEHAVIORAL STRATEGIES

A major goal of the WISEWOMAN program is to determine which behavioral strategies are effective in reducing CVD risk factors among racially and ethnically diverse, underserved, financially disadvantaged women.

Phase One

All three enhanced projects funded during Phase One have completed key analyses. The published results from North Carolina[8] showed that women who received lifestyle counseling through the enhanced intervention reported less fat in their diets at follow-up than did women who received the minimum intervention. Cholesterol and blood pressure profiles generally im-

TABLE 4. RESULTS (JANUARY 1, 2002–DECEMBER 31, 2002) FROM WISEWOMAN STANDARD PROJECTS: PHASE TWO[a]

Variable[b]	*Connecticut*	*Massachusetts*	*Michigan*	*Nebraska*	*South Dakota*	*SEARHC*
Number screened	670	1684	321	1404	921	394
Age, years						
<55	39	72	78	68	86	72
≥55	61	28	22	32	14	28
Race/ethnicity						
White	43	59	77	84	77	0
Black	28	3	17	3	2	0
Hispanic/Latina	25	28	5	11	5	6
American Indian/ Alaska Native	0	0	0	2	14	94
Asian	4	10	1	0	1	0
High total cholesterol[c]	26	20	23	23	17	20
Unaware of high cholesterol	40	60	55	50	60	24
Low HDL[d]	10	8	16	13	17	9
Hypertension[e]	44	24	37	37	25	35
Unaware of hypertension	15	42	26	31	37	26
History of diabetes	11	4	8	9	8	11
Estimated coronary heart disease deaths per 1000 women expected in 10 years[f]	27	14	15	18	11	16
Overweight[g]	36	33	28	26	29	25
Obese[h]	38	26	46	48	42	60
Smoker	17	19	33	23	42	26

[a]Vermont data not shown because only 5 women were screened during 2002.
[b]All data are presented as percentages, except for number screened. Because of missing responses, denominators vary.
[c]≥240 mg/dl.
[d]<40 mg/dl.
[e]Systolic ≥140 mm Hg or diastolic ≥90 mm Hg or taking medication.
[f]Based on a risk projection formula that uses smoking, systolic blood pressure, total cholesterol, and age.
[g]Body mass index = 25–29.9 kg/m^2.
[h]Body mass index ≥ 30 kg/m^2.

proved for both the enhanced and minimum interventions, although the differences between groups were not significant. Results from the Massachusetts and Arizona projects are included in this supplement.[6,7]

Phase Two

Information from Phase Two about the enhanced and standard WISEWOMAN projects was gathered from original applications, research protocols submitted to CDC for Institutional Review Board approval, and interviews with current project staff (Tables 1 and 2). Baseline results from analyses conducted by RTI with use of the MDE database are summarized in Tables 3 and 4. Additional details about the MDE database are provided in a companion paper in this supplement.[23]

Physical activity and nutrition interventions: enhanced projects. The physical activity and dietary strategies that are being tested in enhanced projects in Phase Two are summarized in Table 1. In general, all strategies are based on key concepts from social cognitive theory[24] and the socioecological model,[25] including tailoring, self-monitoring, readiness for change, self-efficacy, small achievable steps, social support, collaborative goal setting, and overcoming barriers.

Three of the five projects (California, North Carolina, and Alaska Southcentral Foundation) are using modifications of the *New Leaf . . . Choices for Healthy Living*,[8] a structured diet and physical activity assessment and intervention tool adapted and expanded from the *Food for Heart Program*.[26–28] The physical activity component of *New Leaf* is based on the CDC/American College of Sports Medicine guidelines, which call for daily accumulation of moderate activity (rather than less frequent and more vigorous activity).[14] The *New Leaf* program uses behavior change the-

ory to help counselors and patients remove obstacles to lifestyle modification (e.g., complexity, cost, lack of time, cultural irrelevance) by developing practical strategies to integrate more activity into participants' daily work and household and social activities.

New Leaf was designed for a Southern, multiethnic, low-literacy population but has been adapted for other populations; a Spanish-language version (*Vida Saludable, Corazón Contento*) was created for the Hispanic/Latina population in North Carolina. In North Carolina, the project also is assessing whether *New Leaf* supplemented with telephone calls, reminders from community health workers, and referrals to community resources is more effective than the usual care provided by a community health center. The California WISEWOMAN project, which is in the process of developing its intervention, is conducting a pilot test to learn how to modify *Vida Saludable, Corazón Contento* for Hispanic/Latina women in that state and to provide counseling with bilingual community health workers. After the pilot test is completed, the intervention will be tested in additional sites. In Alaska, the Southcentral Foundation is using an adaptation of *New Leaf* called *Traditions of the Heart*. The 12-session program, designed in an interactive group format, includes a Native Alaskan traditional wellness component in each session.

The two other states with enhanced projects have also developed 12-week intervention programs. The Illinois WISEWOMAN project has worked with the Cooper Institute to develop a nutrition and physical activity group program based on *Project Active*,[16] called *Women with Heart*. Illinois staff are also developing a Spanish version of this program. In Iowa, Cooperative Extension nutritionists lead a group format that is based on the Dietary Approaches to Stop Hypertension (DASH) diet.[17]

Physical activity and nutrition interventions: standard projects. Four standard projects (Connecticut, South Dakota, Vermont, and Alaska's SEARHC) are using modifications of *New Leaf* in conjunction with other resources. In Connecticut, the project also has adopted the *Physician Assisted Counseling and Evaluation* (PACE) program[18] for physical activity, and in South Dakota, the project has developed a modified version of *Project Active*[16] called *Active Living Every Day*. The Vermont and SEARHC projects supplement *New Leaf* with group interventions focused on nutrition and physical activity (called "wellness circles" in Vermont).

In the three standard projects not using *New Leaf*, staff have developed a variety of intervention strategies. The Massachusetts WISEWOMAN project uses PACE[18] and also refers women to community-based individual or group interventions on nutrition and physical activity. The Michigan project promotes a modified version of the DASH diet[17] and advocates moderate physical activity incorporated into a woman's daily life, negotiates lifestyle contracts after determining a woman's readiness for change, and employs a variety of incentives to motivate change. In Nebraska, Cooperative Extension nutritionists are administering *ABCs for Good Health* (developed by the U.S. Department of Agriculture and based on the *Dietary Guidelines for Americans*[19]) and the *10,000 Steps* program.[20,21] The Nebraska nutritionists help participants set achievable goals and provide pedometers for feedback on physical activity.

Tobacco control interventions: enhanced projects. In all the enhanced projects, staff assess participants' tobacco use and refer women to either a tobacco cessation program or a state quitline.[29] Some projects provide brief counseling, including tips for quitting. Because Native Alaskan women are more likely to use chewing tobacco than are women from other cultures, the Southcentral Foundation WISEWOMAN project targets both cigarette smoking and tobacco chewing. Participants at the Southcentral Foundation complete a tobacco use assessment, receive individual counseling, set goals to stop using tobacco, and may obtain additional counseling at a tobacco cessation clinic. Participants can also request quit aids (e.g., nicotine patches) at no cost.

Tobacco control interventions: standard projects. In all the standard projects, staff refer women to their state quitline.[29] In some states, the quitline service includes up to six telephone contacts. Several projects, including those of SEARHC, Vermont, and Nebraska, are able to track women's participation in the quitline program and thereby assess the quitline's impact on smoking cessation rates. Nebraska provides smoking cessation classes through its state health department, and Alaska's SEARHC project partners with the American Lung Association's *Freedom from Smoking* pro-

gram. Two projects (SEARHC and Vermont) offer nicotine replacement therapy at no cost.

DISCUSSION

It is clear that by serving financially disadvantaged, uninsured, and multiethnic women, WISEWOMAN projects are reaching women who are at high risk of developing CVD and other chronic diseases. Our initial baseline results from Phase Two suggest that many of the women enrolled in WISEWOMAN were unaware of their high blood pressure or their high cholesterol before entering the program. Nearly three quarters of the women who attended baseline screenings were overweight or obese, including a 60% prevalence of obesity in one location. The prevalence of smoking was also higher than would be expected in U.S. women aged 45–64.

Because WISEWOMAN projects are located in a variety of settings and serve women from many different cultural backgrounds, each project strives to adapt evidence-based lifestyle interventions to the culture(s) of the women they serve. We have learned that cultural adaptation involves more than simply translating interventions into a different language. It also requires careful formative research to understand dietary and physical activity practices, facilitators and barriers to behavioral change, and cultural norms. After intervention materials are translated into another language, they are back-translated to ensure that the translation is appropriate for the women who will be receiving the intervention. More detail is provided in other papers in this supplement on how materials have been adapted and used in WISEWOMAN projects.

Although WISEWOMAN projects have helped increase physical activity and improve nutrition,[6–8] it is not entirely clear why our enhanced lifestyle interventions have been less effective in influencing physiological measures (e.g., blood pressure, lipid levels, and anthropometric measures). We suspect that there are critical barriers and facilitators to delivery of complete interventions that, to date, have not been addressed fully in our program. These barriers may include provider skepticism about women's ability to change behavior, social isolation, unsafe neighborhoods, and lack of access to healthful foods. In some locations, for example, women may have to rely on neighborhood stores that do not stock high-quality, affordable fruits and vegetables or low-fat snacks.

Because many of the barriers that women face are structural, WISEWOMAN is now planning to supplement the current approach with a broader societal approach to improve health behaviors. Borrowing from the socioecological model,[25] we are encouraging projects to develop multifaceted interventions that address intrapersonal, organizational, community, and policy influences on health and health behaviors. For example, to strengthen the family and peer support available to participants, some projects now invite family members and friends to attend the interventions. At the organizational level, we are training staff to examine their own attitudes and work collaboratively with women to change their behavior. Organizations are also developing their own creative solutions as a result of receiving WISEWOMAN funding. In North Carolina, for example, a county health department clinic partnered with a community free clinic to extend their operating hours so that WISEWOMAN participants could attend appointments more easily. At the community level, some projects have hired community health workers from participants' neighborhoods to conduct outreach, make telephone calls to encourage attendance at medical examinations and intervention sessions, arrange transportation, help find low-cost medications, and provide other support services. Some projects provide discount passes to encourage exercise in safe environments (e.g., YWCA, local indoor swimming pools) or discount coupons that help women attend community weight loss programs.

As WISEWOMAN projects explore ways to participate as agents of social change, they are building alliances among disadvantaged women and their families, healthcare providers, and neighborhoods. Eliminating social-group disparities in CVD incidence and mortality will likely depend on the strength of these alliances. Our goal in promoting more comprehensive interventions is to empower women to use all available services to facilitate the adoption of a healthier lifestyle. We also hope to garner the social support needed for behavior change, raise providers' expectations, build trust between patients and providers, ensure that healthcare environments effectively address the needs of culturally diverse populations, remove community barriers to a healthy lifestyle, and create advocates

for better healthcare coverage. If WISEWOMAN projects can successfully implement multilevel interventions and demonstrate their effectiveness, this approach is likely to be adopted on a much broader scale. As progress is made toward this goal, the WISEWOMAN program will begin to realize its vision of a world where any woman can access preventive health services and gain the wisdom to improve her health.

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REFERENCES

1. American College of Physicians–American Society of Internal Medicine. No health insurance? It's enough to make you sick. Uninsured women at risk [white paper]. Philadelphia: American College of Physicians–American Society of Internal Medicine, 2001.
2. Collins KS, Hall A, Neuhaus C. U.S. minority health: A chartbook. New York: The Commonwealth Fund, 1999.
3. Smedley BD, Stith AY, Nelson AR, eds. Institute of Medicine. Unequal treatment: Confronting racial and ethnic disparities in health care. Washington, DC: National Academies Press, 2003.
4. The WISEWOMAN Workgroup. Cardiovascular disease prevention for women attending breast and cervical cancer screening programs: The WISEWOMAN projects. Prev Med 1999;28:496.
5. Viadro CI, Farris RP, Will JC. The WISEWOMAN projects: Lessons learned from three states. J Wom Health 2004;13:529.
6. Stoddard AM, Palombo R, Troped PJ, Sorensen G, Will JC. Cardiovascular disease risk reduction: The Massachusetts WISEWOMAN project. J Wom Health 2004;13:539.
7. Staten LK, Gregory Mercado KY, Ranger-Moore J, et al. Provider counseling, health education, and community health workers: The Arizona WISEWOMAN project. J Wom Health 2004;13:547.
8. Rosamond WD, Ammerman AS, Holliday JL, et al. Cardiovascular disease risk factor intervention in low-income women: The North Carolina WISEWOMAN project. Prev Med 2000;31:370.
9. Will JC, Massoudi B, Mokdad A, et al. Reducing risk for cardiovascular disease in uninsured women: Combined results from two WISEWOMAN projects. J Am Med Wom Assoc 2001;56:161.
10. Centers for Disease Control and Prevention. WISEWOMAN. Available at *www.cdc.gov/wisewoman/* Accessed March 1, 2003.
11. National Cholesterol Education Program. Third report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Bethesda, MD: National Heart, Lung, and Blood Institute, NIH, 2001. NIH publication 01-3670.
12. Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. The seventh report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension 2003;42:120.
13. American Diabetes Association. Clinical practice recommendations 2003. Diabetes Care 2004;27, Supplement 1.
14. Pate R, Pratt M, Blair S. Physical activity and public health: A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. JAMA 1995;273:402.
15. Murray D, Wolfinger R. Analysis issues in the evaluation of clinical trials: Progress toward solutions in SAS/STAT MIXED. J Community Psychol 1994;22 (Special Issue):140.
16. Dunn AL, Marcus BH, Kampert JB, et al. Reduction in cardiovascular disease risk factors: 6-month follow-up from Project Active. Prev Med 1997;26:883.
17. Vollmer WM, Sacks FM, Ard J, et al. DASH-Sodium Trial Collaborative Research Group. Effects of diet and sodium intake on blood pressure: Subgroup analyses of the DASH-sodium trial. Ann Intern Med 2001;135:1019.
18. Calfas KJ, Sallis JF, Zabinski MF, et al. Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. Prev Med 2002;34:153.
19. United States Department of Agriculture. Dietary guidelines for Americans, 2000. Available at *www.usda.gov/cnpp/DietGd.pdf* Accessed March 1, 2003.
20. Lindberg R. Active living on the road with the 10,000 Steps program. J Am Diet Assoc 2000;100:878.
21. Iwane M, Arita M, Tomimoto S, et al. Walking 10,000 steps/day or more reduces blood pressure and sympathetic nerve activity in mild essential hypertension. Hypertens Res 2000;23:573.
22. CDC. Cigarette smoking among adults—United States, 2001. MMWR 2003;52:953.
23. Finkelstein EA, Wittenborn JS, Farris RP. Evaluation of public health demonstration programs: The effectiveness and cost-effectiveness of WISEWOMAN. J Wom Health 2004;13:625.
24. Bandura A. Social foundations of thought and action: A social-cognitive theory. Englewood Cliffs, NJ: Prentice-Hall, 1986.
25. McLeroy K, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health Educ Q 1988;15:351.
26. Keyserling T, Ammerman A, Davis C, et al. A randomized, controlled trial of a physician-directed treatment program for low income patients with high

blood cholesterol: The Southeast Cholesterol Project. Arch Fam Med 1997;6:135.
27. Ammerman AS, Haines PS, DeVellis RF, et al. A brief dietary assessment to guide cholesterol reduction in low-income individuals: Design and validation. J Am Diet Assoc 1991;91:1385.
28. Ammerman AS, DeVellis BM, Haines PS, et al. Nutrition education for cardiovascular disease prevention among low-literacy populations—Description and pilot evaluation of a physician-based model. Patient Educ Counsel 1992;19:5.
29. Zhu SH, Anderson CM, Tedeschi GJ, et al. Evidence of real-world effectiveness of a telephone quitline for smokers. N Engl J Med 2002;347:1087.

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Review

Cardiovascular Health Interventions in Women: What Works?

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ABSTRACT

Women's Cardiovascular Health Network members representing 10 Prevention Research Centers completed a literature review of approximately 65 population-based studies focused on improving women's cardiovascular health through behavior change for tobacco use, physical inactivity, or diet. A framework was developed for conducting the search. Databases (Medline, Psychlit, Smoking and Health, Cumulative Index to Nursing and Allied Health Literature) of studies published from 1980 to 1998 were searched. The review was presented at a meeting of experts held in Atlanta, Georgia. Output from the meeting included identification of what has worked to improve cardiovascular health in women and recommendations for future behavioral research. Additional information is available at *www.hsc.wvu.edu/womens-cvh*. Cardiovascular health interventions geared toward women are scant. Based on the available studies, program components that emerged as effective included personalized advice on diet and physical activity behaviors and tobacco cessation, multiple staff contacts with skill building, daily self-monitoring, and combinations of strategies. Recommendations for community-based tobacco, physical activity, and diet interventions are discussed. A few overarching recommendations were to (1) conduct qualitative research to determine the kinds of interventions women want, (2) examine relapse prevention, motivation, and maintenance of behavior change, (3) tailor programs to the stage of the life cycle, a woman's readiness to change, and subgroups, that is, minority, low socioeconomic, and obese women, and (4) evaluate policy and environmental interventions. The effects of cardiovascular interventions in women have been inappropriately understudied in women. Our review found that few studies on cardiovascular risk factor modification have actually targeted women. Hence, adoption and maintenance of behavior change in women are elusive. Intervention research to improve women's cardiovascular health is sorely needed.

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INTRODUCTION

In 1997, the Centers for Disease Control and Prevention (CDC) formed the Women's Cardiovascular Health Network of 10 Prevention Research Centers (Appendix A). One charge of the Network was to identify interventions that promote cardiovascular health in women. This report includes the findings from the literature review and the research recommendations generated thereafter.

EPIDEMIOLOGY OF WOMEN AND CARDIOVASCULAR DISEASE

Cardiovascular diseases are the leading cause of mortality among women of all major racial and ethnic groups in the United States. Approximately one of five women has some form of cardiovascular disease, and women are more likely to die of cardiovascular disease than from the next 16 causes of death combined.[1] More women than men have died of cardiovascular disease in every year since 1984, and its relative decline in recent years has been slower among women.[1,2] Despite the prevalence of cardiovascular disease, surveys reveal that women perceive their risk of getting breast cancer as higher than their risk of developing cardiovascular disease.[3,4]

Cardiovascular disease risk factors can be classified as biological, behavioral, and psychosocial. Biological risk factors include hypertension, dyslipidemia (high total and high low-density lipoprotein [LDL] cholesterol, high triglycerides, low high-density lipoprotein [HDL] cholesterol), obesity, and diabetes. Behavioral risk factors include tobacco use, physical inactivity, and poor diet. Psychosocial risk factors include low socioeconomic status, insufficient social support, depression, and type A personality. Socioeconomic disparities, such as low education and income levels, correlate with cardiovascular disease mortality, morbidity, and risk factors among women.[5,6] The findings of the few studies on psychosocial factors in women have been inconsistent.[7–12] Primary prevention strategies are essential to improve cardiovascular health because the major established risk factors for cardiovascular disease are highly prevalent in women.[13]

Tobacco use

Overall, 30% of cardiovascular morbidity and mortality are directly caused by tobacco use, and the risk is dose dependent.[14–16] In 1994–1995, the age-adjusted prevalence of current tobacco use was 33% among American Indian and Alaskan Native women, 25% among white women, 22% among African American women, 15% among Hispanic women, and 5% among Asian/Pacific Islander women.[17] The prevalence of cigarette use is highest in women ages 18–44 years (29%) and women with lower income or educational level or both (33%).[18–20]

Physical inactivity

Physical inactivity is a major risk factor for cardiovascular disease. Active women experience less coronary heart disease than sedentary women.[21] About 30% of American women do not participate in any leisure physical activity,[22] and as women age, activity levels decline further. Women with less than a high school education or a low income report the highest rates of inactivity: 47% and 41%, respectively.[21]

Diet

Dietary components as well as the whole diet are related to the major cardiovascular disease risk factors. Diets high in saturated fatty acids and cholesterol increase the risk for heart disease, and diets high in plant foods (soy, nuts, fruits and vegetables, whole grains, legumes) and fiber are associated with reduced risk.[21] In the total population, total fat, saturated fat, monounsaturated fat, and dietary cholesterol, as a percentage of total calories, decreased between 1970 and 1974 and 1988 and 1991.[23] Among women ages 30 years and older, about 15%–20% are meeting recommendations for percentage of daily calories from total fat, 14%–23% for saturated fat, 13%–23% for carbohydrates, 70%–81% for dietary cholesterol, and $<5\%$ for dietary fiber.[24]

MATERIALS AND METHODS

Working groups completed a literature review on epidemiology, tobacco use, physical inactivity, diet, multiple risk factors, and psychosocial factors. The working groups used a framework

based on the National Academy of Medicine Medical Subject Headings (MeSH) terms for selecting studies to be reviewed (Fig. 1). Medline, Psychlit, Smoking and Health, and the Cumulative Index to Nursing and Allied Health Literature databases of literature published from 1980 through 1998 were searched. Other references were obtained from citations within studies selected for review.

Studies included in the review were primary prevention, population-based, behavioral research focused on interventions directed at changing health behaviors (tobacco use, physical inactivity, or diet) and psychosocial factors (stress, depression, and social support) related to cardiovascular health in adult women (18 years and older). The studies had to report outcome data on tobacco use, physical inactivity, diet, and blood lipids as primary outcome variables and blood pressure, body weight, or body mass index (BMI) as secondary outcome variables. Because the key impetus for conducting the review was to determine what interventions have worked in women, we reviewed only papers where the sample was at least two-thirds female. The studies were categorized by site of the intervention: healthcare, worksite, religious organization, or community organization. Sample size was not a criterion for study selection. The review was presented at a meeting of experts in December 1998 (Appendix B). At this meeting, groups, divided by the six content areas noted, generated recommendations for behavioral research geared toward improving cardiovascular health in women. This report describes the literature review and the groups' recommendations.

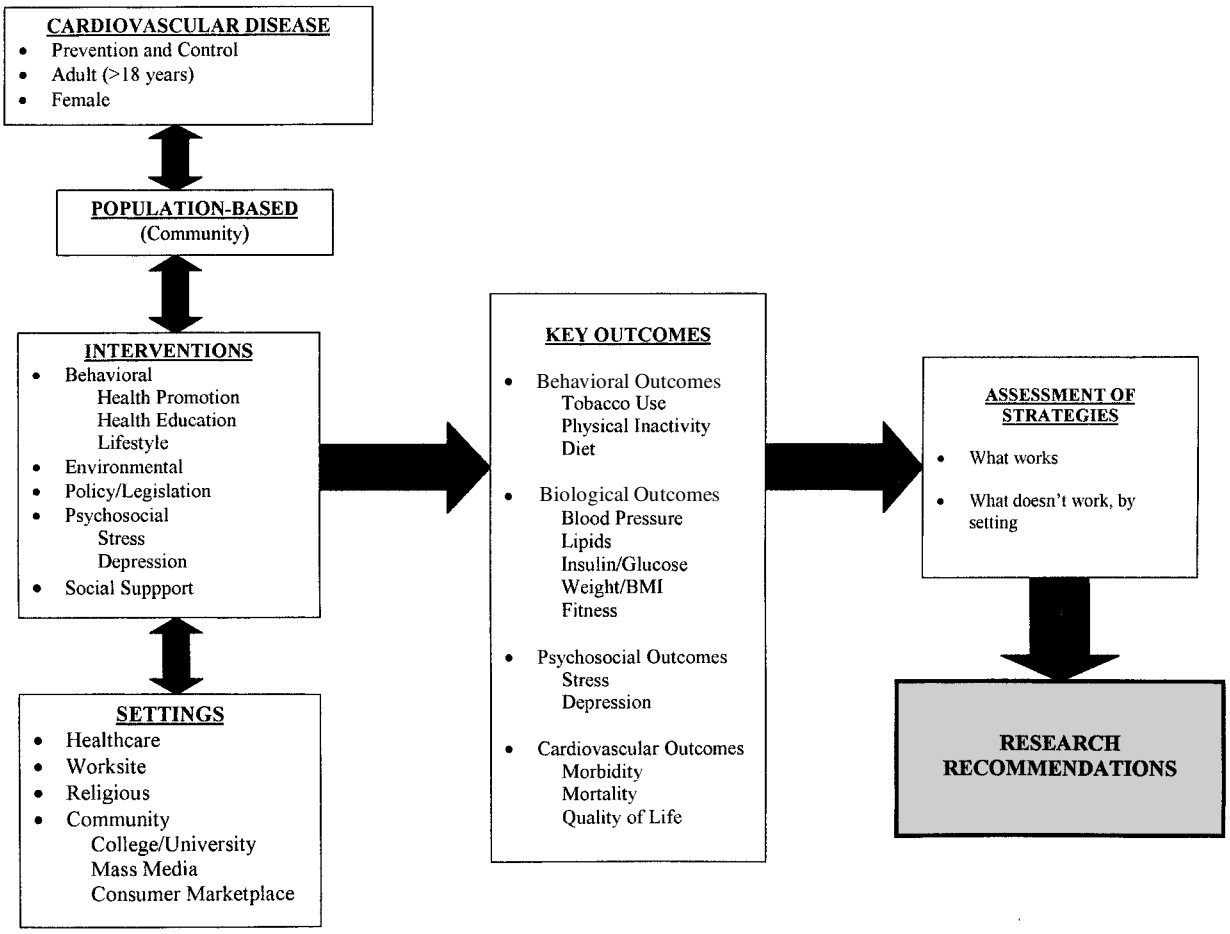

FIG. 1. Women's Cardiovascular Health Network framework for selecting studies (Mesh terms).

INTERVENTIONS TARGETING TOBACCO USE IN WOMEN

Sixteen intervention studies on tobacco cessation met the inclusion criteria for the literature review. A critical time for women to cease tobacco use is during pregnancy, when motivation to protect the fetus is high.[19,25] Some women (15%–25%) stop smoking when they learn of their pregnancy; the rest reduce tobacco use by half. [19,26–31] As most women return to their former tobacco use patterns within 4 weeks postpartum, the greatest public health challenge is maintenance of tobacco-free status.[30,32] None of the reported methods were successful at reducing relapse.[33,34] Overall, tobacco use cessation rates are less among low-income women (6%–14% versus 23%–40%) and minority women, partially because of lack of access to healthcare.

Healthcare settings

Tobacco interventions during pregnancy can be divided into three levels: usual care, mini-interventions,[20,25,26,28,32] and multicomponent interventions.[19,25–32,35,36] Usual care consists of 2–3 minutes of counseling on the pregnancy-related risks of smoking and benefits of quitting given during the initial prenatal visit. This level of intervention produces cessation rates of 2%–3%.[26,28,29,37] Mini-interventions, which include individual advice to stop using tobacco and distribution of educational pamphlets, increase cessation rates to 6%–10%.[20,25,26,28,32]

Multicomponent interventions provide some combination of the following: brief counseling at each prenatal visit, self-help manuals, multiple contacts, incentives, social support, buddy systems, contracts with providers, tip sheets outlining other options, goal setting each visit, setting a quit date, and keeping a smoking diary. These interventions raised quit rates to 10%–25%.

A key component of all programs was strong, clear, personalized counsel to stop using tobacco. Increased duration of one-on-one counseling was associated with increased success. Problem-solving and skills training, social support, and multiple contacts with providers, both in person and via telephone and mailings, were important. More seemed to be better. Positive predictors of cessation included less cigarette use and higher educational and income level, with quit rates of >25% in women who had graduated from high school or were not welfare recipients.[19,20,25,27,29,32,33] A strong negative predictor was regular exposure to other smokers.[19,20,27,32]

Less traditional cessation techniques have also been used.[38–40] Using social learning theory, a videotape of lower-income women, aged 25–29 years, describing their smoking cessation experience was used as an intervention for peers.[38] Five of 26 women in the intervention group quit using tobacco versus 0 of 30 in the comparison group. Although videotaping was well accepted among women, only 53% of the women receiving the video actually watched it. Another innovative intervention strategy involved checking prenatal serum samples for cotinine, a major metabolic product of nicotine, and sending a self-help manual to the women who had positive results. Physicians provided interpretation and counseling.[39] Using birth weight as an outcome, the infants of intervention patients of the 70 compliant physicians had an average 66 g higher birth weight (3291 g versus 3225 g, $p = 0.03$) than controls. Another less traditional strategy for tobacco use cessation in pregnant women was hypnosis. This was not effective in increasing quit rates.[40]

Worksite settings

Much research has been done on the effectiveness of worksite smoking cessation interventions, but none have been targeted exclusively to women. A meta-analyis [41] showed that worksite interventions produce a 10%–30% reduction in smoking. The most successful results are achieved among high-socioeconomic status employees, heavy smokers, and employees at smaller service occupation worksites. Women and men responded similarly in these nontailored interventions. Overall, the intensity of the program, the number of intervention contacts with smokers, and the facilitation of social opportunities for cessation were more important than the specific messages delivered by the program.

Glasgow et al.[42] conducted one of the few studies with a large sample of women (80%). A 6-week smoking cessation program was examined in five financial institution worksites. Four of the five worksites competed to achieve the highest quit rate. Although the study did not include a control group, cessation maintenance at 6 months (15%) was similar to that found in a more rigorous study,[43] which was unique in that it offered

the option of complete cessation or reducing tobacco use. This option increased participation rates among heavier smokers. However, the program was most successful at achieving complete cessation in lighter smokers.

Many other worksite interventions included women[44–47] but did not compare the results in men versus women and, thus, did not identify interventions that were successful in women specifically. Tobacco policies at the worksite may have less of an impact on women's cessation. A total worksite smoking ban was combined with a group program, hypnosis, exercise, relaxation audiotapes, and a booster session.[43] In this comprehensive intervention, 71% of smokers participated in group activities and achieved a 12-month abstinence rate of 15%. Men (19% abstinence) had higher abstinence rates than women (14% abstinence) following policy implementation. From the studies to date, it is not clear what worksite intervention works best to increase cessation in women.

Religious organization settings

Very few studies have examined the effectiveness of smoking cessation interventions implemented through religious organizations. Two studies conducted interventions in African American churches.[48,49] Strategies included forming a tobacco cessation coalition, one-on-one paraprofessional counseling, *Call It Quits* or *Don't Let Your Dreams Go up in Smoke* self-help booklet designed specifically for African Americans, a devotional booklet, gospel quit nights, countywide smoking cessation contests, school poster contests, sermons, quitter testimony, lay counselors, group support, spiritual audiotapes, and scripturally guided cessation booklets. No significant differences were observed between control and intervention groups or between men and women.

Community settings

Most of the community-based studies for smoking cessation combined mass media interventions with more individualized approaches (e.g., self-help manuals, telephone counseling).[50–56] Strategies included a televised smoking cessation program with follow-ups (i.e., updates on television program participants' abstinence), self-help materials from the American Lung Association or other organizations, and classes. Quit rates of about 6% have been reported at up to 24 months follow-up. Higher rates are reported initially (up to 16%), but these are not sustained. Only one study reported quit rate by gender: a 12% abstinence rate was observed 3 months after the intervention in women.[54] Although women were more likely to participate in television/self-help interventions, they were no more likely than men to quit and remain abstinent.[50,51,53–55] Thus, mass media did not appear to help women with cessation. Heavy smokers and those with stronger support, irrespective of gender, were the ones most likely to quit.

Only one study has looked at intervention components and success rates in women and men.[56] A cessation maintenance newsletter was more likely to be used by women, and those who used the newsletter were more likely to be abstinent.

The effectiveness of smoking cessation contests has also been evaluated by several studies. A complex Finnish study[57] compared the effectiveness of three different combinations of interventions. The control group viewed a broadcast televised smoking cessation program that involved a contest. For one study group, the broadcast program and contest were supplemented with a locally televised smoking cessation program. Another study group included those components plus the support of a community organization. At 6 months, total abstinence was 19%, with women being less successful (18%) than men (24%). Although women were less abstinent than men, they viewed more sessions of the televised smoking cessation program and participated in the smoking cessation contest more often than men. In women, greater participation was not related to higher abstinence rates.

A unique study was conducted among black women with children enrolled in Head Start.[58] The women were randomized to a control or intervention group and attended an eight-session smoking cessation class led by peers. The class included tips for involving nonsmoker support in their quit effort. Abstinence rates at the 6-month follow-up were higher for the intervention group (12%) than for the controls (6%). The success of this intervention was attributed to the social support available to women through Head Start and the unique focus of the intervention on protecting children from environmental tobacco smoke.

The effects of a community-based comprehensive smoking cessation program (mass media, such as television, radio, fliers, pamphlets, billboards, bumper stickers, and newspaper ads),

outreach workers, telephone counseling, self-help manuals (i.e., American Lung Association manuals), smoking cessation group programs, and a biannual raffle were studied in Hispanic women.[59] Acculturation did not affect quit rates in the women, but overall success was attributed to the development of culturally appropriate intervention messages and materials.

The most definitive study of communitywide approaches to smoking cessation was conducted in 22 communities and included 11 control and 11 intervention groups over a 4-year period.[60] Intervention settings included healthcare, mass media, community events, and worksites. There were no significant differences in quit rates between women and men.

Summary

Pregnancy and the postpartum period are opportune times to treat tobacco dependence in women. More intense interventions with individualized approaches yield the best outcomes. Even though most pregnant women who reduce or quit smoking will relapse postpartum, cessation or reduction of smoking during the pregnancy is likely to bestow long-term benefit to the infant by decreasing the chance of low birth weight and its resultant health problems. More work needs to be done to keep mothers from resuming their tobacco habit in the postpartum period.

Community-based approaches to smoking cessation have not been particularly effective for women. The limited success of these programs depends on the population being served and the unique combination of intervention components. Smoking cessation interventions through Head Start may offer a unique opportunity to reach women who do not respond to other community-based interventions. In general, women are more likely to participate in community-based programs but are less likely to quit smoking as a result than are men. Low-income women are also a challenge for developing culturally appropriate materials and intervention strategies.

Table 1. Information Gaps in Interventions Targeting Tobacco Use in Women

Pregnant women
Intervention in nonclinical settings
Studies that include women younger than 18 years, long-term follow-up, and strategies for lowering relapse rates, verification of tobacco use status
Other women
Strategies for success

Table 2. Research Recommendations for Interventions Targeting Tobacco Use in Women

Use teachable moments, e.g., pregnancy and postpartum
Conduct qualitative research across the life cycle
Address social support, weight, and root causes of tobacco use, taking into account race and gender
Conduct comprehensive interventions (policy, education)
Focus on primary prevention
Target high-risk groups (low socioeconomic status or ethnic/minority groups)
Use innovation, e.g., videotapes and verification feedback
Intervene in nonclinical settings
Use adjunct pharmacotherapy
Emphasize stages of change as program outcomes
Combine physical activity with smoking cessation

Information gaps and research recommendations

Recommendations to prevent young women from smoking include elucidating the root causes of tobacco use initiation and dependence, particularly with respect to social and economic inequalities, body image, and available social support systems. A major opportunity to improve the tobacco dependence treatment in women is to place greater emphasis on the prevention of relapse among those who quit smoking during pregnancy, thus using the motivation of women during this time to make a permanent behavior change to improve their cardiovascular health. Although there are more studies on tobacco cessation than on any other risk factor, many information gaps remain (Table 1). Research is recommended to move the field forward (Table 2).

INTERVENTIONS TARGETING PHYSICAL INACTIVITY IN WOMEN

Nineteen studies met the inclusion criteria. Achieving optimal physical activity levels is difficult for many women. Interventions to change physical activity behaviors varied in type of intervention (face-to-face or by letter), length (6 weeks–2 years), mode (combination of aerobics, walking, or stationary bicycle), frequency of activity (2–5 days per week), duration (20–60 min-

utes), and format (group or home based). None of the investigations were tailored to gender, ethnicity, socioeconomic status, or stage of the life cycle.

Strategies involved training in problem solving, self-monitoring, goal setting, relapse prevention, incentives and contracts, feedback, boosters, support, and encouragement either face-to-face or by telephone. A theoretical framework guided 11 of the studies.

Healthcare settings

The two studies conducted in healthcare settings were guided by the transtheoretical model and social cognitive theory.[61,62] Both demonstrated that minimal exercise counseling by a physician that was matched to the subject's needs or readiness to change was successful in producing a short-term increase in physical activity. Behavioral outcomes were measured through the subjects' self-reports of physical activity. These studies were not specific to women.

Worksite settings

Seven studies involved worksite interventions, although only two had supervised, onsite exercise programs.[63,64] A relapse prevention program was no more successful than a reinforcement program of awards and lottery tickets in increasing adherence in previously sedentary female university employees. Instructor influence and personal self-efficacy (belief in one's ability to attain goals) contributed to higher attendance at an exercise program among another sample of female university employees.[64] Instructor influence was thought to enhance the subjects' beliefs in personal capabilities or confidence in being able to attend the program.

Several behavioral strategies were tried in middle-aged employees at an aerospace corporation. Relapse prevention strategies along with self-monitoring and biweekly phone contact were more successful in helping people adopt a moderate-intensity, home-based exercise program than was baseline instruction alone. Self-monitoring of home-based exercise increased functional capacity (measured by maximum oxygen consumption [$V_{O_{2max}}$]) at 6 months in employees using this strategy.[65] Daily self-monitoring was more effective in increasing the amount of exercise than was weekly self-monitoring.[66]

More frequent telephone contacts also increased activity levels in female university employees.[67] Self-reported walking (minimum 20 minutes/day, 3 times/week) was higher in women who were contacted once a week versus every 3 weeks. More frequent highly structured prompting, however, was as effective as frequent low-structure prompting. Thus, making contact appears to be more important than the content of the contact.

Contact via mail was explored in female clerical workers.[68] Those who received a packet encouraging them to integrate more activity into their daily activities reported significantly more weekly leisure activity compared with women who received a packet encouraging them to follow a more traditional structured exercise program or with the control group, who received a fitness feedback packet only. Women who received the traditional structured exercise program packet reported more leisure activity than did the control group.

In a comprehensive behavioral approach,[69] investigators compared the results of using a time-intensive, behavioral template that included contracts, verification procedures, incentives, lotteries, and team competitions along with 15 1-hour meetings with the results of a group that only attended the meetings without the template. Adherence, defined as a percentage of weeks in which the women met the criteria (aerobic activity four times/week), was significantly higher for the group receiving the template than for the control group. It was not possible to identify which of the behavioral components were most beneficial.

Community settings

Multiple strategies have been used in community settings to increase physical activity. Physical activity, assessed by self-report and an objective measure of body movements, increased following a 2-year intervention compared with controls.[70,71] After an initial 8-week training program, women had the option to walk as a group or alone. According to the self-reports, physical activity remained higher in the intervention group than in the control group for the 10-year follow-up.[72] In another study, tailoring activity materials to women's readiness to adopt physical activity produced an increase in physical activity.[73]

In another study, log sheet self-monitoring,

coupled with staff support and feedback, increased exercise adherence at a health club compared with self-monitoring alone.[74] A study of middle-income minority women found that a minimal-contact behavior change intervention (mailed materials and six structured counseling telephone sessions) was no more effective than a very low intensity educational intervention (a single 5-minute telephone call and educational information) in increasing walking.[75] Home-based exercise with telephone contact increased adherence (as long as 2 years) in both high-intensity and moderate-intensity training more than a group-based format.[76] In a 6-month intervention,[77] a lifestyle physical activity program with a goal to accumulate moderate intensity activity and a structured exercise program both increased energy expenditure and aerobic fitness over baseline. Subjects in the lifestyle program met in small groups to receive training in problem solving. It appears that a lifestyle approach is as effective for increasing physical activity and fitness as is structured exercise. Adherence remained high for both groups at the end of 1 year.[78]

Several researchers examined the effects of behavioral strategies in combined exercise and nutrition interventions. Such strategies as telephone calls, incentives, transportation, and child care were used to encourage attendance of African American women at a 10-week nutrition and supervised exercise program.[79] This was the only intervention adapted to the concerns of the participants. Interpretation of results, however, is limited because there was no control group and no group who received either exercise or diet alone.

Strategies used in a study that aimed to increase activity and modify diet in middle-aged women included stimulus control, goal setting, assertiveness training, and self-monitoring.[80] Telephone contacts reinforced concepts. The intervention group reported a significant increase in physical activity compared with controls. In another study, aerobic fitness increased in a diet-plus-supervised exercise group compared with a diet-only and a control group.[81] Although both intervention groups received encouragement, by the 6-month follow-up, over half of the women had stopped exercising.[82]

Summary

Behavioral strategies, such as daily self-monitoring, feedback, contracts, and incentives, have been effective at increasing physical activity levels in study participants. Whether these changes in physical activity behavior are sustained as a lifestyle change is unknown. Women did respond better to lifestyle physical activity recommendations versus structured exercise recommendations. Finding ways for women to incorporate activity has been a challenge. For many women, the home-based format for physical activity has advantages over more traditional formats, such as sessions in a gym or health club. Home-based activities can be carried out between household chores and other activities as time allows. Methods to increase the energy expenditure of everyday activities through lifestyle changes could be a way to improve exercise and fitness in women who struggle to take time out of their busy day for physical activity. To increase adherence to scheduled programs, time of day and day of week must be flexible to accommodate women's caregiving and work roles.

Information gaps and research recommendations

Research on physical activity in women has been constrained by a lack of good measurement tools (Table 3). Measures varied from women reporting that they are more active than they were before the intervention to counting the number of times a woman attended a structured exercise program. Quantifying the physical activity of women through questionnaires designed for men fails to capture typical female activity expended in housework and unstructured exercise, such as dancing around the home or actively playing with children. Dishman [83] states that when measuring the degree of adherence to habitual exercise behavior, the type of exercise, its frequency, intensity, and duration must all be considered. Studies that use an exercise log come closest to

Table 3. Information Gaps in Interventions Targeting Physical Inactivity in Women

Assessment tools for physical activity specific to women
Barriers, sociodemographic factors, development of life stages, and seasonal variations related to physical activity
Studies measuring physical activity for longer periods after the intervention concludes

TABLE 4. RESEARCH RECOMMENDATIONS FOR INTERVENTIONS TARGETING PHYSICAL INACTIVITY IN WOMEN

Tailor interventions to life stage, readiness to be physically active
Focus on lifestyle physical activity
Tailor programs to subgroups (e.g., elderly, ethnic minorities, obese)
Use multiple channels to reach women
Conduct environmental (e.g., safe walking trails) and policy (e.g., daily physical education in schools) interventions
Develop tools to accurately assess physical activity

meeting these strict criteria. Objective measures of frequency, duration, and intensity of physical activity, such as those provided by a heart rate monitor or accelerometer, would strengthen future studies.

To date, our understanding of exercise behavior in women is restricted primarily to economically advantaged Caucasian women. We have little understanding of the interaction among a woman's ethnic and cultural background, health status, and past experience or how these characteristics influence barriers, such as family obligations and lack of personal time, that each woman must overcome to increase physical activity. Before developing physical activity interventions for women who are not economically advantaged, factors inhibiting their motivational readiness to undertake physical activity must be identified. Only then can interventions be tailored to each woman's needs.

To improve activity levels in women, we need an understanding of which behavioral intervention strategies are effective, what formats (group or home-based activities) are more attractive to women, and what type of exercise women can incorporate most readily into their lives. Despite the limitations in methods, findings suggest that adoption and maintenance of physical activity can be enhanced by a variety of behavioral management strategies. Clearly, women benefit from strategies that provide external reinforcement, such as that provided by healthcare professionals or instructor feedback and encouragement. Although they may be costly, such strategies as brief telephone prompts provide promising alternatives to face-to-face interaction. Other recommendations for future research are given in Table 4.

INTERVENTIONS TARGETING DIET IN WOMEN

Despite improvements in blood cholesterol levels in the general population, 76% of women over age 50 need dietary intervention to lower their levels.[84] Because cardiovascular disease remains the leading cause of death in women, effective strategies to help women achieve healthy dietary practices need to be developed.[85] Given the number of women needing diet intervention, one would expect to find much research on how to change dietary behaviors in women. In fact, the opposite is true. Very few studies have been geared to women, nor have they addressed the needs of women at various stages of life. We reviewed interventions that addressed the question of what produces dietary behavior change in women. We believe that the ideal intervention should strictly focus on women and their needs, but this has rarely been done in research studies.

The nutrition working group identified eight studies that used nutrition interventions to reduce cardiovascular risk in free-living women.[86–93] All but one study included both men and women in the sample. In the mixed groups, women comprised 67%–81% of the total sample. Only one study targeted a minority group.[92] Five studies were short term.[86,87,91–93]

Healthcare settings

Three studies conducted in healthcare settings met the inclusion criteria; one targeted women. None were conducted in one major group of primary care providers of women, that is, obstetricians/gynecologists. Two of the studies suggested that low-intensity interventions may be effective in producing short-term dietary change. The Partners in Prevention Program[86] tested the effectiveness of tailored messages to promote increased fruit and vegetable consumption and decreased fat consumption. Family practice patients ($n = 558$) were randomized to one of three groups: tailored, nontailored, or control. The tailored message group received one nutrition information packet of materials about the stages of change, baseline dietary intake, barriers, and self-efficacy for behavior change. The nontailored group received dietary guidelines materials generic for the population. The control group received no materials. At 4 months, fat intakes were significantly reduced by 23%, 9%, and 3%, in the

tailored, nontailored, and control groups, respectively. There was no increase in fruit and vegetable intake, possibly due to seasonal factors; baseline intakes were taken in the fall, and follow-up was in the winter months when intakes may generally be lower. A second low-intensity intervention conducted in 28 medical practices (67% women) showed that a physician-delivered motivational message with a self-help book produced small but significant decreases in fat consumption and increases in fiber intake.[93] People in the action/maintenance stage of adoption of a low-fat diet had the greatest decreases in fat intake. No changes were observed in total cholesterol level, BMI, or weight.

The dietary study targeted to women was the Women's Health Trial, a feasibility study of adopting and sustaining a low-fat diet in women at high risk for breast cancer.[88] Although this was a cancer prevention study and these women may be more motivated than the general population, it is the most intensive intervention for dietary change reported to date, and they did measure serum lipids and dietary behaviors that meet our inclusion criteria. Women randomized to the intervention group participated in small group sessions led by registered dietitians, which integrated nutrition and behavioral principles, particularly self-monitoring, self-correcting, and skill building. By the end of 3 months, 80% of women had met their fat intake goal. This high success rate was maintained by 70% of women at 36 months follow-up. Predictors of fat consumption were education level, eating-related support, reaction to dietary plans (adjusting fat intake based on the previous meal consumed), outcome efficacy (belief that eating a low-fat diet would decrease breast cancer incidence), and personal efficacy (individual belief that one is capable of changing behavior). This trial was successful because the women were motivated, the intervention was intense, and behavioral theories to produce change were used.

Worksite settings

Most worksite diet interventions have focused on men and cancer outcomes. Few measure diet behaviors, and few use behavioral theory. Only one worksite intervention for eating behavior change met the criteria, the Staff Healthy Heart Project.[87] Although this project was not targeted to women, 70% of the hospital employees who volunteered for the project were women. Employees with total blood cholesterol levels >200 mg/dl were randomized to receive self-help diet materials or to attend five 1-hour group sessions led by a registered dietitian. Recruitment was high, but participation proved difficult because of workplace barriers. Only 35% of subjects attended three or more classes. Despite low participation, subjects in the nutrition course consumed significantly fewer calories and more fiber than the other group. There were no significant differences in blood lipid levels between the two groups. However, data analysis was complicated by the high attrition rate. In particular, young women were more likely to drop out of the study. Strategies are needed to maintain the participation level throughout the course of worksite interventions if they are to affect women's cardiovascular health.

Religious organization settings

One church-based, cholesterol education program was conducted in six predominantly black churches.[91] All participants were screened for blood pressure, blood cholesterol, and weight, received brief counseling, and then were randomized to the intervention or the control group. The intervention group participated in six weekly, 1-hour nutrition education classes taught by lay peers. Both groups experienced significant decreases in blood cholesterol levels that were not significantly different from each other. One explanation for the lack of a significant difference between the groups was that more control group women returned for follow-up measures, which indicates that they have been more highly motivated than the intervention group.

Community settings

Two community studies met the criteria. The HELP Your Heart Eating Plan was an early nutrition intervention conducted through the Texas Extension Home Demonstration Clubs for normolipemic community-dwelling members (mostly women).[89] During the first year, the intervention group attended four nutrition classes led by a registered dietitian and two follow-up sessions, one at 24 months and one at 36 months. Although the subjects achieved some success in lowering blood cholesterol and triglyceride levels during the first year, the reductions were not

maintained through the course of the study. Thus, adults made dietary changes in the short term but were not able to sustain those changes on their own. The researchers question whether large-scale community studies can ever achieve lasting behavior change without continued education and support.

The DIET program, a low-intensity weight reduction and cardiovascular health intervention, was conducted in two older adult communities.[90] Cognitive behavioral therapy was used to optimize the use of time by professional support. Workbooks and videotapes served as the primary educational tools. Four workshops led by registered dietitians reinforced the workbooks and videotapes. Participants experienced significant weight loss (3.2 kg), decreased blood glucose (0.3 mmol), and increased levels of HDL cholesterol (0.15 mmol). The data suggest that a cognitive behavioral diet and exercise program can help older adults lose weight and positively affect HDL cholesterol levels and blood glucose levels, thus reducing cardiovascular risk. The number of workbook chapters completed was positively associated with the degree of weight loss. The success of the program was due to the combination of a behavioral-based intervention and intervention with healthcare providers. Longer-term follow-up is needed to see if behavior changes can be maintained.

Summary

The scarcity of dietary interventions tailored to women makes it difficult to conclude what strategies are successful for women. To date, the most successful dietary intervention was an intensive intervention led by registered dietitians for the Women's Health Trial.[88] Possible reasons for the success of this intervention include the intensity of the intervention, the use of behavioral theory for intervention development, and participant empowerment.

Table 5. Information Gaps in Interventions Targeting Diet in Women

Psychosocial factors affecting dietary behavior (e.g., types of support)
Factors affecting adoption and sustainability of diet behavior changes
Impact of societal factors on dietary intake
Effects of mental health on dietary intake
Mediating factors in behavior change
Strategies to facilitate adherence to a healthy diet
Ethnic and socioeconomic effects on dietary patterns

Table 6. Research Recommendations for Interventions Targeting Diet in Women

Identify effective ways to adopt and maintain healthy diets
Study strategies to facilitate adherence
Evaluate the effect of community-based behavioral strategies on dietary intake
Develop cost-effective ways to modify diets
Conduct qualitative research and participatory programs
Use a comprehensive approach tailored to life cycle, readiness, and other key factors
Use a total diet approach, i.e., diet for prevention of all chronic disease
Use teachable moments
Develop approaches for minority women and those of low socioeconomic status

Information gaps and research recommendations

There is a major gap in nutrition research regarding adoption as well as sustainability of dietary behavior change. How women respond to environmental interventions is unknown, as is the best channel for reaching women. For nutrition interventions in women, there are more gaps than there is knowledge (Table 5). Consequently, there is a great need for future research (Table 6).

INTERVENTIONS TARGETING MULTIPLE RISK FACTORS

Eight studies selected for this section of the literature review used multifactorial interventions directed at physical inactivity, diet, and tobacco use in an attempt to reduce the incidence of cardiovascular disease.[94–101] Because the type of interventions varied, it is not possible to say which strategy worked best in the community. None were designed to study women primarily, but all included women and reported findings based on gender. Each was conducted over a number of years, and each used cross-sectional surveys for the analyses.

Healthcare settings

The Family Heart Study was the only study on women conducted in a healthcare setting.[94] The incidence of cardiovascular disease was reduced

by 15% over the course of the intervention and was attributable to all behavioral risk variables, that is, diet, physical inactivity, and tobacco use. However, the extent to which each contributed is not clear.

Community settings

Major community intervention trials include the Swedish Community Intervention Program,[95] Bootheel Heart Health Project,[101] Minnesota Heart Health Program,[96,97] Pawtucket Heart Health Program,[98] and the German community study.[99] Cardiovascular health outcomes measured were blood cholesterol, blood pressure, BMI, diet, physical activity, and tobacco use.

Change in blood pressure. Blood pressure was significantly lowered in the German community intervention.[99] Systolic blood pressure was 129 mm Hg for the intervention group and 131 mm Hg for the control group ($p < 0.0001$). Diastolic blood pressure was 78.7 mm Hg for the intervention group and 80.4 mm Hg in the control group ($p < 0.0001$). In addition, hypertension decreased in the intervention group by 21%, and this reduction was greater for women than men. Others have found similar reductions in blood pressure[100] or no change at all.[96]

Change in cholesterol levels. In a Swedish cohort, the prevalence of hypercholesterolemia in women decreased from 53% to 36% over the intervention's 5-year period.[95] A significant treatment effect on blood cholesterol was observed in the Coronary Risk Factor Study[100] but not in the Minnesota Heart Health Program.[96] Community interventions have positively affected cholesterol levels.

Change in obesity. In the 3-year Bootheel Project,[101] more women had a BMI >30 after the intervention, 31% versus 24%. The Minnesota Heart Health Program [96,97] and Coronary Risk Factor Study[100] found no significant treatment effect on BMI. The Pawtucket Heart Health Program[98] reported that women were twice as likely as men to attempt weight loss (odds ratio 2.4). However, men were 40% more likely than women to succeed in weight loss. To date, community studies have been ineffective in decreasing obesity prevalence.

Change in diet. Dietary changes were reported following the Bootheel project.[101] Overall consumption of fruits and vegetables increased in the intervention group and decreased in the control group ($p = 0.03$)

Change in physical activity. The Pawtucket Heart Health Program[98] found that women were more likely than men to begin an exercise program (44% women versus 36% for men) but less likely to continue an exercise program when compared with men (61% women versus 67% men). This finding is similar to those of other risk factor interventions in which women participate but do not maintain their involvement in the long run.

Change in tobacco use. Tobacco use decreased less in women than in men (27% compared with 33%) in the Pawtucket Heart Health Program.[98] A 1% reduction in tobacco use was observed in the Minnesota Heart Health Program.[96] Other studies[95,99–101] did not find a change in tobacco use prevalence among women in community interventions, although there were significant decreases in men.

Summary

In the last 10 years, there have been several large-scale multifactorial interventions with the goal of reducing cardiovascular disease risk. However, none of these multifactorial interventions targeted women specifically, and there was little difference between any individual intervention components that were specific to gender and those that were applied in both genders. The results of some of the studies reviewed are promising, as they indicate that multifactorial interventions may decrease a woman's risk of cardiovascular disease. Generally, such risk factors as blood pressure, cholesterol level, and tobacco use changed as a result of the interventions. However, the other risk factors (obesity as measured by weight change, dietary patterns, and level of physical activity) were not significantly affected. These results suggest that multifactorial approaches may not be ideal for women. The effects of an intervention that targets one risk factor as opposed to an intervention that addresses many may offer women a more focused, intense strategy for behavior change. More research is needed to address the optimal intervention approach for women.

TABLE 7. INFORMATION GAPS IN INTERVENTIONS TARGETING MULTIPLE RISK FACTORS IN WOMEN

Multifactorial interventions targeting cardiovascular health
Use of theory to guide intervention development and analysis
Descriptions of recruitment and retention
Interventions specific for women

Information gaps and research recommendations

The community studies leave many gaps. First, there has been difficulty in maintaining intervention follow-up, and attrition has been high in many longitudinal studies. Second, behavioral theory, if used to guide the interventions, was not addressed in the publications. Third, methods for assuring cultural sensitivity of materials as well as research and intervention staff have been lacking. Fourth, interventions that are empowering (skill building) need to be developed to assure sustainability beyond the grant. Fifth, the interactive effects of changes in each risk factor have not been explored. Gaps for multiple risk factor intervention studies are given in Table 7, and research recommendations are shown in Table 8.

INTERVENTIONS TARGETING PSYCHOSOCIAL INTERVENTIONS IN WOMEN

Social support

Social networks and support have been found to predict long-term mortality risk from a number of causes, especially from cardiovascular disease.[102] Although much of the research has been limited to men, there is evidence for the negative effects of social isolation on cardiovascular outcomes in women. Most social support interventions designed to affect cardiovascular health have been conducted to improve outcomes after a coronary event in men.[103] For primary prevention, social support has been effective as a strategy for individual behavior change for tobacco use, diet, and physical inactivity.[104] Community-based interventions modifying support systems and changing supportive environments for primary prevention of cardiovascular disease are rarely done. Two interventions included social support: Health Works for Women, a worksite intervention that targets blue-collar working women for risk factors of tobacco use, physical inactivity, diet, and stress using natural (lay) helpers,[105] and a peer-support intervention for cardiovascular risk among African American women aged 40 and older using lay health advisors to encourage both individuals and community groups to make the change needed to reduce cardiovascular risk.[106]

TABLE 8. RESEARCH RECOMMENDATIONS FOR INTERVENTIONS TARGETING MULTIPLE RISK FACTORS IN WOMEN

Use theory-based interventions
Target women and subgroups
Assure cultural sensitivity of staff and materials
Measure process and intermediate outcomes
Include measures of intervention intensity
Incorporate skill-building methods for sustaining long-term results
Use qualitative methods to develop and test interventions during the formative phase before conducting the main study
Determine the interactive effect of change of one risk factor on another (e.g., diet/tobacco use; tobacco use/physical inactivity)
Evlaluate the impact of different components of a comprehensive program on health behavior

TABLE 9. INFORMATION GAPS IN INTERVENTIONS TARGETING PSYCHOSOCIAL RISK FACTORS IN WOMEN

How psychosocial factors influence behavioral risk
Conduct psychosocial interventions

Psychosocial stress

There is evidence for a link between psychosocial stress and coronary disease,[107] although

TABLE 10. RESEARCH RECOMMENDATIONS FOR INTERVENTIONS TARGETING PSYCHOSOCIAL RISK FACTORS IN WOMEN

Conduct epidemiological studies of the association between social ties and cardiovascular health
Consider the effect on risk factors of all social factors, including social support
Gain a better understanding of different dimensions of social support (functional, structural) for behavior change
Study the types of stress women experience (multiple roles, occupational stress) and how stress differs by social charcteristics
Study psychosocial factors as mediating variables for behavior change
Conduct qualitative studies of women's perceptions of stress

most such research has been conducted with men. Stress may be associated with greater risk of cardiovascular disease in women because of occupational factors of lower-level jobs with greater job strain, low pay, and unequal distribution of household responsibilities. Women are also more likely to experience stress because of poverty, and they have fewer environmental resources for support. Many of the population-based interventions for stress management have been conducted in worksite settings[108] using a variety of techniques, including biofeedback, meditation, and muscle relaxation. Most of these interventions assessed behavioral or cognitive outcome measures (job satisfaction, depression, anxiety, somatic complaints) and were conducted in men.

Information gaps and research recommendations

Few community-based preventive psychosocial interventions to address cardiovascular health have been designed exclusively for women. More interventions are needed to minimize women's stress in workplace settings, especially for those who experience increased stress from role strain and conflict. Women need to be involved in designing stress reduction interventions that are relevant and appropriate. Given the strong evidence for a relationship between social networks and social support and health outcomes, more attention is warranted for implementing interventions at the level of the social network[109] and acknowledging and using the strength of women's interpersonal networks.[110] Gaps for psychosocial risk factor intervention studies are given in Table 9, and research recommendations are given in Table 10.

CONCLUSIONS

Despite the high prevalence of risk factors and morbidity and mortality from cardiovascular disease in women, few clinical or public health interventions for primary prevention have targeted women.[85,111] For the most part, the effects of cardiovascular health interventions have been understudied in women. Much work needs to be done to improve cardiovascular health in women and to learn the best ways of helping women to adopt and sustain healthy lifestyle behaviors.

REFERENCES

1. American Heart Association. 1999 Heart and stroke statistical update. 1998.
2. Centers for Disease Control and Prevention. Trends in ischemic heart disease deaths in United States, 1990–1994. MMWR 1997;46:146.
3. Legato MJ, Padus E, Slaughter E. Women's perceptions of their general health, with special reference to their risk of coronary artery disease: Results of a national telephone survey. Women's Health 1997; 6:189.
4. Pilote L, Hlatky MA. Attitudes of women toward hormone therapy and prevention of heart disease. Heart 1995;129:1237.
5. Kaplan GA, Kiel JE. Socioeconomic factors and cardiovascular disease: A review of the literature. Circulation 1993;88:1973.
6. Winkleby MA, Kraemer HC, Ahn DK, Varady AN. Ethnic and socioeconomic differences in cardiovascular disease risk factors: Findings for women from the Third National Health and Nutrition Examination Survey, 1988–1994. JAMA 1998;280:356.
7. Barrett-Connor E. Sex differences in coronary heart disease. Why are women so superior? Circulation 1997;95:252.
8. Brezinka V, Kittel F. Psychosocial fctors of coronary heart disease in women: A review. Soc Sci Med 1995; 42:1351.
9. Greenlund KJ, Liu K, Gardin J, Dyer AR, McCreath H, Knox S. Psychosocial work characteristics and cardiovascular disease risk factors: The CARDIA Study. Soc Sci Med 1995;41:717.
10. Hellerstedt WL, Jeffery RW. The association of job strain and health behaviors in men and women. Int J Epidemiol 1997;26:575.
11. LaCroix AZ. Psychological factors and risk of coronary heart disease in women: An epidemiologic perspective. Fertil Steril 1994;62:133S.
12. Toobert DJ, Strucker MA, Glasgow RE. Lifestyle change in women with coronary heart disease: What do we know? Women's Health 1998;7:685.
13. Stamler J Established major coronary risk factors. In: Marmot M, Elliott P, eds. Coronary heart disease epidemiology: From aetiology to public health. New York: Oxford, 1992:35.
14. Centers for Disease Control and Prevention. Cigarette smoking among adults in the United States, 1997. MMWR 1998;48:993.
15. Rich-Edwards JW, Manson JE, Hennekens CH, Buring JE. The primary prevention of coronary heart disease in women. N Engl J Med 1995;332:1758.
16. Fiore MC, Jorenby DE, Baker TB. Smoking cessation: Principles and practice based upon the AHCPR guideline, 1996. Behav Med 1997;19:213.
17. U.S. Department of Health and Human Services. Tobacco use among U.S. racial/ethnic minority groups: African-Americans, American Indians and Alaska Natives, Asian-Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General. Atlanta,

GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1998.
18. Centers for Disease Control and Prevention. Tobacco use in the United States, 1990–1999. MMWR 1999; 48:986.
19. Secker-Walker RH, Solomon LJ, Flynn BS, et al. Individualized smoking cessation counseling during prenatal and early postnatal care. Am J Obstet Gynecol 1994;171:1347.
20. Kendrick JS, Zahniser SC, Miler N, et al. Integration smoking cessation into routine public prenatal care: The Smoking Cessation in Pregnancy project. Am J Public Health 1995;85:217.
21. Mosca L, Manson JE, Langer RD, Sutherland SE, Manolio T, Barrett-Connor E. Cardiovascular disease in women: A statement for healthcare professionals from the American Heart Association. Circulation 1997;96:2468.
22. U.S. Department of Health and Human Services. Physical activity and health: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.
23. Ernst ND, Sempos ST, Briefel RR, Clark MB. Consistency between U.S. dietary fat intake and serum total cholesterol concentrations: The National Health and Nutrition Examination Surveys. Am J Clin Nutr 1997;66(Suppl):965S.
24. Kris-Etherton PM, Krummel DA. Role of nutrition in the prevention and treatment of coronary heart disease in women. J Am Diet Assoc 1993;93:987.
25. Hartmann KE, Thorp JM, Pahel-Short L, Koch MA. A randomized controlled trial of smoking cessation intervention in pregnancy in an academic clinic. Obstet Gynecol 1996;87:621.
26. Windsor RA, Lowe JB, Perkins LL, et al. Health education for pregnant smokers: its behavioral impact and cost benefit. Am J Public Health 1993;83:201.
27. Ershoff DH, Dolan Mullen P, Quinn VP. A randomized trial of a serialized self-help smoking cessation program for pregannt women in an HMO. Am J Public Health 1989;79:182.
28. Windsor RA, Cutter G, Morris J, et al. The effectiveness of smoking cessation methods for smokers in public health maternity clinics: A randomized trial. Am J Public Health 1985;75:1389.
29. O'Connnor AM, Davies Bl, Dulberg CS, et al. Effectiveness of a pregnancy smoking cessation program. J Obstet Gynecol Neonat Nurs 1992;21:385.
30. Lillington L, Royce J, Novak D, Ruvalcaba M, Chlebowski R. Evaluation of smoking cessation program for pregnant minority women. Cancer Pract 1986; 3:157.
31. Petersen L, Handel J, Kotch J, Podedworny T, Rosen A. Smoking reduction during pregnancy by a program of self-help and clinical support. Obstet Gynecol 1992;79:924.
32. Nowicki P, Gintzig L, Hebel R, Latham R, Miller V, Sexton M. Effective smoking intervention during pregnancy. Birth 1984;11:217.
33. Ershoff DH, Quinn VP, Dolan Mullen P. Relapse prevention among women who stop smoking early in pregnancy: A randomized clinical trial of a self-help intervention. Am J Prev Med 1995;11:178.
34. Secker-Walker RH, Solomon LJ, Flynn BS, et al. Smoking relapse prevention counseling during prenatal and early postnatal care. Am J Prev Med 1995; 11:86.
35. Wright LN, Pahel-Short L, Hartmann K, Kuller JA, Thorp JM. Statewide assessment of a behavioral intervention to reduce cigarette smoking by pregnant women. Am J Obstet Gynecol 1996;175:283.
36. Hjalmarson AIM, Hahn L, Svanberg B. Stopping smoking in pregnancy: Effect of a self-help manual in a controlled trial. Br J Obstet Gynaecol 1991;98:260.
37. Valbo A, Nylander G. Smoking cessation in pregnancy: Intervention among heavy smokers. Acta Obstet Gynecol Scand 1994;73:215.
38. Secker-Walker RH, Solomon LJ, Geller BM, et al. Modeling smoking cessation: Exploring the use of a videotape to help pregnant women quit smoking. Women's Health 1997;25:23.
39. Haddow JE, Knight GJ, Kloza EM, Palomaki GE, Wald NJ. Cotinine-assisted intervention in pregnancy to reduce smoking and low birth weight delivery. Br J Obstet Gynaecol 1991;98:859.
40. Valbo A, Eide T. Smoking cessation in pregnancy: The effect of hypnosis in a randomized study. Addict Behav 1996;21:29.
41. Fisher KJ, Glasgow RE, Terborg JR. Worksite smoking cessation: A meta-analysis of long-term quit rates from controlled studies. J Occup Med 1990;32:429.
42. Glasgow RE, Klesges RC, Clesges LM, Somes GR. Variables associated with participation and outcome in a worksite smoking control program. J Consult Clin Psychol 1998;56:617.
43. Sorensen G, Lando H, Pechacek TF. Promoting smoking cessations at the workplace. J Occup Med 1993;35:121.
44. Jason LA, Gruder CL, Martino S, Flay BR, Warnecke RB, Thomas N. Worksite group meetings and the effectiveness of a televised smoking cessation intervention. Am J Community Psychol 1987; 15:57.
45. Jason LA, Lesiwitz T, Michaels M, et al. A worksite smoking cessation intervention involving the media and incentives. Am J Community Psychol 1989;17: 785.
46. Millar WJ. Evaluation of the impact of smoking restrictions in a government work setting. Can J Public Health 1988;79:379.
47. Sorensen G, Rigotti N, Rosen A, Pinney J, Pribel R. Effects of a worksite nonsmoking policy: Evidence for increased cessation. Am J Public Health 1991; 81:202.

48. Schorling JB, Roach J, Siegel M, et al. A trial of church-based smoking cessation interventions for rural African-Americans. Prev Med 1997;26:92.
49. Voorhees CC, Stillman FA, Swank RT, Heagerty PJ, Levine DM, Becker DM. Heart, body, and soul: Impact of church-based smoking cessation interventions on readiness to quit. Prev Med 1996;25:277.
50. Danaher BG, Berkanovic E, Gerber B. Mass media-based health behavior change: Televised smoking cessation program. Addict Behav 1984;9:245.
51. Warnecke RB, Langenberg P, Wong SC, Flay BR, Cook TD. The second Chicago televised smoking cessation program: A 24-month follow-up. Am J Public Health 1992;82:835.
52. Warnecke RB, Langenberg P, Gruder CL, Fisher KJ, Jason LA. Factors in smoking cessation among participants in a televised intervention. Prev Med 1989; 18:833.
53. Thompson B, Curry S. Characteristics and predictors of participation and success in a televised smoking cessation activity. Worksite Health Promotion 1994; 8:175.
54. Wheeler RJ. Effects of a community-wide smoking cessation program. Soc Sci Med 1988;27:1387.
55. Sussman S, Dent CW, Wang E, Cruz NTB, Sanford D, Johnson CA. Participants and nonparticipants of a mass media self-help smoking cessation program. Addict Behav 1994;19:643.
56. McFall S, Michener A, Rubin D, et al. The effects and use of maintenance newsletters in a smoking cessation intervention. Addict Behav 1993;18:151.
57. Korhonen HJ, Niemensivu H, Piha T, et al. National smoking cessation program and contest in Finland. Prev Med 1992;21:74.
58. Jones R, Manfredi C, Mermelstein R, Raju N, Thomas V. The Head Start parent involvement program as a vehicle for smoking reduction intervention. Fam Community Health 1994;17:1.
59. VanOss-Marin B, Perez-Stable EJ, Marin G, Hauck WW. Effects of a community intervention to change smoking behavior among Hispanics. Am J Prev Med 1994;10:340.
60. Commit Research Group. Community intervention trial for smoking cessation (COMMIT): I. Cohort results from a four-year community intervention. Am J Public Health 1995;85:183.
61. Calfas KJ, Long BJ, Sallis JF, Wooten WJ, Pratt M, Patrick K. A controlled trial of physician counseling to promote the adoption of physical activity. Prev Med 1996;25:225.
62. Marcus BH, Goldstein MG, Jette A, et al. Training physicians to conduct physical activity counseling. Prev Med 1997;26:382.
63. Marcus BH, Stanton AL. Evaluation of relapse prevention and reinforcement interventions to promote exercise adherence in sedentary females. Res Q Exerc Sport 1993;64:447.
64. McAuley E, Jacobson L. Self-efficacy and exercise participation in sedentary adult females. Am J Health Promotion 1991;5:185.
65. Juneau M, Rogers F, De Santos V, et al. Effectiveness of self-monitored, home-based, moderate-intensity exercise training in middle-aged men and women. Am J Cardiol 1987;60:66.
66. King AC, Taylor CB, Haskell WL, DeBusk RF. Strategies for increasing early adherence to and long-term maintenance of home-based exercise training in healthy middle-aged men and women. Am J Cardiol 1988;61:628.
67. Lombard DN, Lombard TN, Winett RA. Walking to meet health guidelines: The effect of prompting frequency and prompt structure. Health Psychol 1995; 14:164.
68. Cardinal BJ, Sachs ML. Effects of mail-mediated, stage-matched exercise behavior change strategies on female adults' leisure-time exercise behavior. J Sports Med Phys Fitness 1996;36:100.
69. Robison JI, Rogers MA, Carlson JJ, et al. Effects of a six-month incentive-based exercise program on adherence and work capacity. Med Sci Sports Exerc 1992;24:85.
70. Cauley JA, Kriska AM, LaPorte RE, Sandler RB, Pambianco G. A two-year randomized exercise trial in older women: Effects on HDL-cholesterol. Atherosclerosis 1987;66:247.
71. Kriska AM, Bayles C, Cauley JA, LaPorte RE, Sandler RB, Pambianco G. A randomized exercise trial in older women: Increased activity over two years and the factors associated with compliance. Med Sci Sports Exerc 1986;18:557.
72. Pereira M, Kriska A, Day R, Cauley J, LaPorte R, Kuller L. A randomized walking trial in postmenopausal women. Arch Intern Med 1998;158: 1695.
73. Marcus BH, Banspach SW, Lafebvre RC, Rossi JS, Carleton RA, Abrams DB. Using the stages of change model to increase the adoption of physical activity among community participants. Am J Health Promotion 1992;6:424.
74. Weber J, Wertheim E. Relationships of self-monitoring, special attention, body fat percent, and self-motivation to attendance at a community gymnasium. J Sport Exerc Psychol 1989;11:105.
75. Chen AH, Sallis JF, Castro CM, et al. A home-based behavior intervention to promote walking in sedentary ethnic minority women: Project WALK. J Women's Health: Res Gender Behav Policy 1998; 4:19.
76. King AC, Haskell WL, Young DR, Oka RK, Stefanick ML. Long-term effects of varying intensities and formats of physical activity on participation rates, fitness, and lipoproteins in men and women aged 50 to 60 years. Circulation 1995;91:2596.
77. Dunn AL, Garcia ME. Six-month physical activity and fitness changes in Project Active: A randomized trial. Med Sci Sports Exerc 1998;30:1076.
78. Dunn AL. Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness: A randomized trial. JAMA 1999;281:327.

79. Lasco RA, Curry RH, Dickson VJ, Powers J, Menes S, Merritt RK. Participation rates, weight loss, and blood pressure changes among obese women in a nutrition/exercise program. Public Health Rep 1989; 104:641.
80. Simkin-Silverman L, Wing RR, Hansen DH, et al. Prevention of cardiovascular risk factor elevations in healthy premenopausal women. Prev Med 1995;24: 509.
81. Svendsen OL, Hassager C, Christiansen C. Effect of an energy-restrictive diet, with or without exercise, on lean tissue mass, resting metabolic rate, cardiovascular risk factors, and bone in overweight postmenopausal women. Am J Med 1993;95:131.
82. Svendsen OL, Hassager C, Christiansen C. Six months' follow-up on exercise added to a short-term diet in overweight postmenopausal women: Effects on body composition, resting metabolic rate, cardiovascular risk factors, and bone. Int J Obes 1994; 18:692.
83. Dishman R. The measurement conundrum in exercise adherence research. Med Sci Sports Exerc 1994; 26:1382.
84. Sempos CT, Cleeman JI, Caroll MD, et al. Prevalence of high blood cholesterol among U.S. adults. JAMA 1993;269:3009.
85. Kris-Etherton PM, Krummel DA, Champagne C, Kristin M, Abir F. Cardiovascular disease and women's health. Topics Clin Nutr 1995;11:8.
86. Campbell MK, DeVellis BM, Stretcher VJ, Ammerman AS, Devellis RF, Sandler RS. Improving dietary behavior: The effectiveness of tailored messages in primary care settings. Am J Public Health 1994;84: 783.
87. Barratt A, Reznik R, Irwig L, et al. Worksite cholesterol screening and dietary intervention: The Staff Healthy Heart Project. Am J Public Health 1994;84: 779.
88. Bowen DJ, Henderson MM, Iverson D, Burrows E, Henry H, Foreyt J. Reducing dietary fat: Understanding the success of the Women's Health Trial. Cancer Prev Int 1994;1:21.
89. Reeves RS, Foreyt JP, Scott LW, Mitchell RE, Wohlleb J, Gotto AM. Effects of a low-cholesterol eating plan on plasma lipids: Results of a three-year community study. Am J Public Health 1983;73:873.
90. Wylie-Rosett J, Swencionis C, Peters MH, et al. A weight-reduction intervention that optimizes use of practitioner's time, lowers glucose level, and raises HDL-cholesterol level in older adults. J Am Diet Assoc 1994;94:37.
91. Wiist WH, Flack JM. A church-based cholesterol education program. Public Health Rep 1990;105:381.
92. Murray DM, Kurth C, Mullis R, Jeffery RW. Cholesterol reduction through low-intensity interventions: Results from the Minnesota Heart Health Program. Prev Med 1990;19:181.
93. Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH. A dietary intervention in primary care practice: The Eating Patterns Study. Am J Public Health 1997;87:610.
94. Wood DA, Kimmoth AL, Davies GA, et al. Randomized controlled trial evaluating cardiovascular screening and intervention in general practice: Principal results of a British Family Heart Study. Br Med J 1994;308:313.
95. Brannstrom I, Weinehall L, Presson LA, Wester Po, Wall S. Changing social patterns of risk factors for cardiovascular disease in a Swedish Community Intervention Program. Int J Epidemiol 1993;22: 1026.
96. Luepker RV, Murray DM, Jacobs DR Jr, et al. Community education for cardiovascular disease prevention: Risk factor changes in the Minnesota Heart Health Program. Am J Public Health 1994;84:1383.
97. Luepker RV, Rastam L, Hannan PJ, et al. Community education for cardiovascular disease prevention: Morbidity and mortality results from the Minnesota Heart Health Program. Am J Epidemiol 1996; 144:351.
98. Carleton RA, Lasater TM, Assaf AR, Feldman HA, McKinlay S. The Pawtucket Heart Health Program: Community changes in cardiovascular risk factors and projected disease risk. Am J Public Health 1995; 85:777.
99. Hoffmeister GB, Mensink GBM, Stolzenberg H, et al. Reduction of coronary heart disease risk factors in the German Cardiovascular Prevention Study. Prev Med 1996;25:135.
100. Rossouw JE, Jooste PL, Charlton DO, et al. Community-based intervention: The Coronary Risk Factor Study (CORIS). Int J Epidemiol 1993;22:428.
101. Brownson RC, Smith CA, Pratt M, et al. Preventing cardiovascular disease through community-based risk reduction. The Bootheel Heart Health Project. Am J Public Health 1996;86:206.
102. Berkman LF. The role of social relations in health promotion. Psychosom Med 1995;57:245.
103. King KB. Psychosocial and social aspects of cardiovascular disease. Ann Behav Med 1997;19:264.
104. Zimmerman RS, Connor C. Health promotion in context: The effects of others on health behavior change. Health Ed Q 1989;16:57.
105. Tessaro I, Campbell M, Benedict S, et al. Developing a worksite health promotion intervention: Health Works for Women. Am J Health Behav 1998;22:434.
106. Cornell C, Stalker V, Racznski J, et al. Peer support intervention for cardiovascular risk among African-American women aged 40 and older. Prevention Research Centers Annual Meeting, Atlanta, GA, 2000.
107. Elliott SJ. Psychosocial stress, women and heart health: A critical review. Soc Sci Med 1995;40:105.
108. Murphy LR. Stress management in work settings: A critical review of the health effects. Am J Health Promotion 1996;11:112.
109. Berkman LF, Leo-Summers L, Horwitz RI. Emotional support and survival after myocardial infarction. Ann Intern Med 1992;117:1003.

110. Marshall AA, Smith SW, McKeon JK. Persuading low-income women to engage in mammography screening: Source, message, and channel preference. Health Communication 1995;7:283.
111. Contento I, Balch G, Bronner YL, et al. The effectiveness of nutrition education and implications for nutrition education policy, programs, and research: A review of research. J Nutr Educ 1995:27:278.

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APPENDIX A

WOMEN'S CARDIOVASCULAR HEALTH NETWORK

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APPENDIX B

INVITED ATTENDEES AT WOMEN'S CARDIOVASCULAR HEALTH MEETING OF EXPERTS

ATLANTA, GEORGIA, DECEMBER 1998

Barbara Ainsworth, Ph.D., M.P.H., associate professor, University of South Carolina
Alice Ammerman, Dr.P.H., R.D., assistant professor, University of North Carolina
Lynda Anderson, Ph.D., public health educator, Centers for Disease Control and Prevention
Terry Bazzarre, Ph.D., scientific consultant, American Heart Association

WOMEN'S CARDIOVASCULAR HEALTH INTERVENTIONS **135**

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Lynne Blair, M.P.A., B.S., manager, Ministry of Health
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Jennie Kim, M.H.S., policy analyst, U.S. Public Health Service
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Bess Marcus, Ph.D., associate professor, Brown University
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Lead Review Article

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Nutrition and Physical Activity Interventions to Reduce Cardiovascular Disease Risk in Health Care Settings: A Quantitative Review with a Focus on Women

Sara Wilcox, Ph.D., Deborah Parra-Medina, Ph.D., Melva Thompson-Robinson, Dr.P.H., and Julie Will, Ph.D.

The authors conducted a quantitative literature review of the impact of 32 diet and physical activity (PA) interventions delivered in health care settings on cardiovascular disease risk factors. Intervention effects were relatively modest but statistically significant for PA, body mass index or weight, dietary fat, blood pressure, and total and low-density lipoprotein serum cholesterol. Intervention effects were generally larger for samples with a mean age >50 years and for studies with <6 months follow-up. Type of comparison group, type of intervention, and use of a behavior theory did not have a consistent impact on intervention effects. Few studies focused on persons of color, although the results from these studies are promising.

Introduction

The U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services*, considered a "gold standard" for evidence-based recommendations for clinical preventive services,[1] recommends that all healthy adults be counseled regarding diet and exercise. *Healthy People 2010*,[2] a nationwide health promotion and disease prevention agenda, has set the following goals for physical activity and dietary counseling: 85% of physicians will counsel their patients about physical activity (PA) by the year 2010, and 75% of physician office visits made by patients with cardiovascular disease (CVD), diabetes, or dyslipidemia will include counseling or education related to diet and nutrition by the year 2010.

These guidelines and goals are based on evidence that poor dietary habits and sedentary lifestyles contribute to excessive morbidity and mortality,[3] and that physician counseling for diet and exercise is effective but not practiced often enough to have a significant impact.[4] Sedentary lifestyle and poor nutrition are major risk factors for CVD, the leading cause of death for American men and women.[5,6]

A number of reviews have documented the significant ability of physician counseling to effect general lifestyle changes,[7] as well as to promote PA[8–10] and a healthful diet.[8] Since the publication of these reviews, however, a number of additional health care–based PA and dietary interventions have been conducted. Further, all reviews to date have been narrative reviews that have not examined the *magnitude* of nutrition and PA counseling effects. Finally, previous reviews have not highlighted gender and race/ethnicity issues. We were interested in the effects of these interventions for women, especially women of color.

This updated literature review focuses on dietary and PA counseling interventions delivered in health care settings that were aimed at reducing CVD risk factors. We only considered articles that were focused exclusively on women or that included women as participants. This review also quantified the magnitude of the interventions' effects by computing effect sizes (correlation coefficients) for all studies. This review was conducted as part of the Heart Healthy and Ethnically Relevant Tools project in which our primary interest was dietary and PA interventions for CVD risk reduction in women in general, and in women of color in particular. Thus, a final purpose of this

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review was to highlight health care interventions conducted with women of color.

Methods

Search Strategy

We searched four electronic databases for the years 1980–2000: Medline, Cumulative Index to Nursing and Allied Health Literature, Current Contents Connect, and PsychINFO. The following key words were used for the diet search: nutrition or diet combined with counseling, blacks, African Americans, women, cardiovascular disease, hypertension, cholesterol, weight, family practice, and primary health care. The following key words were used for the physical activity search: exercise or PA combined with counseling, blacks, African Americans, women, physicians, family practice, primary health care, intervention studies, randomized controlled trial, patient education, and health promotion. Because index searches have been shown to yield less than two-thirds of relevant articles,[11,12] we also searched the bibliographies of original and review articles already retrieved.

Inclusion Criteria

The review was restricted to English language reports of trials conducted in health care settings that investigated the effects of PA or dietary advice on CVD risk factors. Additional criteria for the studies included were: a CVD risk factor was included as an outcome variable (i.e., systolic blood pressure [SBP], diastolic blood pressure [DBP], total serum cholesterol, high-density lipoprotein [HDL] cholesterol, low-density lipoprotein [LDL] cholesterol, body mass index [BMI, kg/m^2] or body weight, dietary fat, energy intake, dietary fiber, PA, or exercise); the report was a primary study rather than a review or practice guideline; the sample included women ages ≥18 years; the study was published between 1980 and 2000; and a control group or minimal-intervention group was included. Studies that focused on pharmacotherapy were not reviewed.

Computation of Effect Sizes

In order to provide an index of the relative magnitude or clinical meaningfulness of the intervention effect, we computed effect sizes for all outcome variables specified by our search criteria. In essence, this procedure removes the scale of measurement (e.g., mm Hg, kcal) and converts all outcomes to a standard metric so that comparisons between effects from different studies are possible.

The Pearson Product Moment Correlation r was selected as our standard metric. The use of r was chosen over other metrics for three reasons articulated by Rosenthal.[13] First, studies often do not provide enough data to calculate an accurate effect size d. Second, r can be used to convert dependent t-tests to estimates of effect sizes, whereas d cannot. The third reason has to do with the simplicity of interpreting r in practical terms: methods exist for easily converting r to an improvement in success rate associated with the intervention or treatment.[13]

The computation of correlation coefficients was aided by the software program Meta-Analysis 5.3.[14] The manner in which correlation coefficients were computed was generally dictated by the amount of information reported in the study. Often, we were required to compute or convert exact statistics (e.g., F, t, χ^2) or exact P values to r. A number of studies used within-subject variance to compute the differences in change between the control and intervention groups. In these cases, we essentially computed a dependent t-test and converted this value to r. When this was not the case and means and standard deviations (or standard errors) were reported at baseline and follow-up, we subtracted the change in the control group's score from the change in the intervention group's score, divided this difference by the pooled standard deviation at baseline, and then converted this value to r. We used conventional formulas, as specified by Rosenthal[13] and Wolf,[15] to compute correlation coefficients.

The correlation coefficient is a useful indicator of clinical efficacy. It can be squared, and this value represents the variance in the outcome variable that is explained by intervention status. Thus, a correlation coefficient of 0.30 indicates that 9% of the variance in total serum cholesterol, for example, is explained by intervention status, and that 91% ($1 - r^2$) is explained by other factors.[15]

We further coded each correlation coefficient according to the type of CVD risk factor (PA or exercise, stage of readiness for change in PA, BMI or weight, dietary fat, energy intake, dietary fiber, general diet outcome, stage of readiness for change in diet, SBP, DBP, total, LDL or HDL serum cholesterol and potential moderating characteristics (age, behavior theory specified, type of intervention, comparison group, and follow-up period). We noted whether or not a study reported the use of a behavior theory (e.g., Social Cognitive Theory, Transtheoretical Model) to guide the intervention. Type of intervention was coded as diet-only, PA-only, or combined intervention.

Owing to a limited number of results for some of the CVD risk factors, we only examined moderating effects for PA or exercise, BMI or body weight, dietary fat, SBP, and total cholesterol. We did not compute correlation coefficients that compared two or more distinct interventions (in the absence of a control or minimal intervention group).

Results

Summary of Articles

A total of 45 health care–based intervention papers were reviewed and are included in Table 1. Of these, two did not report adequate data to compute correlation coefficients, five reported on an ongoing intervention or were descrip-

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings

Physical Activity Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Blair et al.[16] King et al.[17]	RCT *n* = 874 45% women	Primary care (United States) TTM, SCT 29% minority 35–75 years M = 51 years	I_1: Clinician & health educator advice I_2: I_1 + in-clinic health educator counseling, interactive mail I_3: I_2 + 2 years telephone counseling, classes	6 and 24 months	Energy expenditure and fitness	Results not yet reported	Results not yet reported
Bull and Jamrozik[18]	RCT *n* = 763 65% women ≥18 years M = 50 years	Family practice (Australia) TTM, SCT	C: No intervention I: Verbal advice from clinician and mailed standard or tailored pamphlet	1, 6, and 12 months	Percent active	More patients in I were active at 1 and 6 months (40%, 38%) than patients in C (31%, 30%) (P <0.02). Differences were NS at 12 months	1 month = 0.09 6 month = 0.09 12 months = 0.05
Bull et al.[19]	RCT *n* = 763 65% women ≥18 years M = 50 years Sedentary	Family practice (Australia) TTM, SCT	C: No intervention I_1: Verbal advice from clinician and mailed general pamphlet I_2: Verbal advice from clinician and mailed tailored pamphlet	1, 6, and 12 months	Percent active	At 1 month, 31% of C, 38% of I_1, and 41% of I_2 patients were active. At 6 months, 30%, 39%, and 36% were active. At 12 months, differences were NS	1 month, I_1 versus C = 0.07 1 month, I_2 versus C = 0.10 6 months, I_1 versus C = 0.09 6 months, I_2 versus C = 0.06 12 months, I_1 versus C = 0.03 12 months, I_2 versus C = 0.06
Bull et al.[20]	RCT *n* = 272 83% women ≥18 years M = 39 years Undcractive	Family medicine (Australia) TTM	C: Usual care I_1: Tailored and personalized mailing I_2: General and personalized mailing I_3: General and generic mailing	3 months	Change in level of activity	Differences between groups were NS. All groups showed an increase in these variables at FU	I_1 versus C = 0.12 I_2 versus C = 0.08 I_3 versus C = 0.11
Burton et al.[21]	RCT *n* = 3097 64% women 13% minority ≥65 years	Primary care (United States) NR	C: Pamphlet on good health practices I: Offered two preventive examinations and counseling session	24 months	Sedentary lifestyle	Group assignment unrelated to sedentary lifestyle	Patients in good health = −0.00 Patients in poor health = 0.04
Calfas et al.[22]	QE *n* = 255 84% women 28% minority ≥18 years M = 39 years	Multispecialty clinics (United States) TTM, SCT	C: Usual care I: Physician counseling and stage-matched materials; 10-minute booster call; optional tip sheets	4–6 weeks	Stage of change, minutes/week walking, hours/week moderate-intensity PA	52% of I patients versus 12% of C patients moved to active stage (P <0.0001). I increased walking by 40 minutes, C increased walking by 10 minutes (P <0.05)	stage = 0.39 PA average = 0.12

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Physical Activity Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Goldstein et al.[23] Pinto et al.[24]	RCT *n* = 355 65% women 3% minority M = 66 years	Primary care (United States) SCT, TTM, HET	C: Standard care I: Stage-matched physician counseling, written PA prescription, patient manual, FU appointment with physician, newsletters	6 weeks, 8 months	Stage of change, PASE	At 6 weeks, 89% of I were in preparation or action versus 74% of C patients (P <0.001). At 8 months, differences were NS. PASE scores increased in both groups at 6 weeks, but decreased at 8 months (between-group differences were NS)	6 weeks stage = 0.19 8 months stage = –0.12 6 weeks PA = –0.02 8 months PA = 0.01
Graham-Clarke & Oldenburg[25]	RCT *n* = 758 26% women 18–69 years	General practice (Australia) TTM	C: Clinician CVD risk assessment and feedback I_1: C + patient video I_2: I_1 + self-help booklet	4 and 12 months	Stage of change, energy expenditure	From baseline to 4 months, more C patients progressed to a higher stage (27%) than I_1 (23%) or I_2 (17%) (P <0.05). From baseline to 12 months, differences between groups were NS. Energy expenditure increased in the entire sample over the 12 months (P <0.001), but group differences were NS	Pre-Post: 4 months stage = –0.14 12 months stage = 0.01 12 months pre-post kcal= 0.16 Insufficient data reported to compare groups
Harland et al.[26]	RCT *n* = 523 58% women 40–64 years	General practice (United Kingdom) TTM	C: Printed health information and community resources I_1: C + one brief MI I_2: I_1 + community facility voucher I_3: C + six intensive MI I_4: I_3 + community facility voucher	12 weeks and 12 months	Sessions of moderate or greater PA	At 12 weeks, 38% of I increased PA versus 16% of C (P <0.001). At 1 year, 26% of I versus 23% of C increased PA (NS)	12 weeks, I versus C = 0.19 1 year, I versus C = 0.03
Kerse et al.[27]	RCT *n* = 267 54% women ≥65 years M = 73.5 years	General practice (Australia) NR	C: Usual care I: Geriatric health educational program for practitioner	12 months	Frequency and duration of PA	At FU, I walked 44 minutes/week more than C (P <0.05)	Minutes/week = 0.13
Lewis and Lynch[28]	RCT *n* = 396 77% women ≥18 years M = 35.5 years	Family medicine (United States) NR	C: Usual care (but ~40% received exercise advice) I: 2–3 minutes of resident exercise advice and educational handout	1 month	Minutes/week of exercise	I increased by 108.7 minutes/week versus –23.7 for C (P <0.01)	Minutes/week = 0.20
Marcus et al.[29]	QE *n* = 63 72% women ≥50 years M = 67 years	Primary care (United States) TTM, SCT	C: Completed the study prior to physician training session I: Stage-matched physician counseling (3–5 minutes), written educational materials, and 1-month FU visit offered	1 month	PASE	For I, PASE scores increased from 148 to 154 versus 125 to 125 for C (NS)	PASE = 0.14

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Physical Activity Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Naylor et al.[30]	QE *n* = 294 77% women M = 42.4 years	Primary care (United States) TTM	C: Usual care: advised according to current practice standards I_1: Stage-based written materials and verbal advice; I_2: Stage-based written materials only; I_3: Non-staged verbal advice	2 and 6 months	Stage of change, intensity-weighted minutes/week	Differences between groups at 2 and 6 months FU were NS. All patients, on average, progressed to a higher stage at 2 and 6 months FU (P <0.05)	Insufficient data to compute *r*
Schultz[31]	RCT *n* = 54 37% women <1% minority 36–65 years M = 48.8 years	PET scan center (United States) P/OMI	I_1: Educational strategies, including verbal and written information I_2: I_1 + behavioral strategies and telephone FU	2, 4, 6, and 12 weeks	Frequency and duration of moderate to vigorous PA	Both groups increased frequency (P <0.05), but I_2 increased more than I_1 (P <0.05) at 6 weeks, but not at 12 weeks. Both groups increased duration (P <0.001), but differences between groups were NS	*r* not computed—study compared two interventions
Stevens et al.[32]	RCT *n* = 714 60% women 13% minority 45–74 years M = 59 years Inactive	General practice (United Kingdom) NR	C: Information on local facilities, PA, and health sent I: Invitation letter from practitioner to attend an exercise consultation at a local facility and 10-week exercise program sent	8 months	Episodes of moderate and vigorous exercise	I versus C patients reported more moderate (5.09 versus 3.64) and total episodes (5.95 versus 4.43) of PA at 8 months FU (P <0.05). Differences between groups for vigorous activity were NS	Insufficient data to compute *r*
Swinburn et al.[33]	RCT *n* = 491 57% women M = 49 years	General practice (New Zealand) NR	I_1: Verbal PA advice by general practitioner I_2: I_1 + written PA prescription	6 weeks	Walking, sports, and other leisure-time PA	Participation in any PA increased to a greater extent in I_2 (51% to 86%) than in I_1 (56% to 77%) (P <0.01). More I_2 (73%) than I_1 (63%) increased PA (P = 0.02). Duration increased in both groups, but differences between groups were NS	*r* not computed—study compared two interventions
Taylor et al.[34]	RCT *n* = 345 26% women 40–70 years M = 55 years Patients were smokers, hypertensive, or overweight	Community health centers (United Kingdom) NR	C: Leaflets on preventing CVD I: C + exercise referral + offered 20 half-price exercise sessions over a 10-week period at leisure center	8, 16, 26, and 37 weeks	Moderate and vigorous PA, kcal $kg^{-1}day^{-1}$, SBP, DBP, BMI	More moderate minutes/week at 8 weeks in I than C (247 versus 145, P <0.05), but not other times. More vigorous minutes/week at 8 weeks in I than C (49 versus 21, P = 0.06) and 16 weeks (59 versus 21, P <0.05), but not other times. I expended more energy than C patients at 8 weeks (35 versus 34, P <0.01) but not at other times. No group differences in SBP, DBP, or BMI	8-week-average PA = 0.27 16-week-average PA = 0.21 26/37-week-average PA = 0.03 16-week-SBP = 0.01 26/37-week-SBP = 0.04 16-week-DBP = −0.01 26/37-week-DBP = 0.04 16-week-BMI = 0.08 26/37-week-BMI = 0.06

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted In Health Care Settings (continued)

Diet Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Ammerman et al.[35]	QE *n* = 138 100% minority	General practice (United States) SCT	C: Usual care I: Dietary risk assessment, culturally specific nutrition education materials, and physician counseling	8 months	Discussion of dietary issues, knowledge	Patients discussed dietary issues more often with doctor and reported greater understanding of what doctor told them	No CVD effect sizes to be computed
Baron et al.[36]	RCT *n* = 368 49% women 25–60 years M = 42 years	General practice (United Kingdom) NR	C: No dietary advice I: Given nurse instruction regarding optimal body weight, dietary advice, and booklet on basics of diet, recipes, and local restaurants	12 months	Fiber: perceived effort at increasing fiber and decreasing fat; total, LDL, and HDL cholesterol	For women: At 3 months, 70% of I versus 2% of C were trying to increase fiber; 80% of I versus 1% of C were trying to decrease fat. At 12 months, 42% of I versus 3% of C were trying to increase fiber; 38% of I versus 0% of C were trying to decrease fat. Grams of fiber increased for I but not C at 3 months (5.9 versus −0.7 g) and 12 months (2.5 versus −1.0 g). No between-group differences for total, LDL, or HDL cholesterol at 3 or 12 months	For women: 3-month-average dietary change attempts = 0.76 6-month-average dietary change attempts = 0.48 3-month-fiber = 0.45 6-month-fiber = 0.26 3-month-total cholesterol = −0.04 6-month-total cholesterol = −0.03 3-month-LDL cholesterol = 0.02 6-month-LDL cholesterol = −0.02 3-month-HDL cholesterol = −0.05 6-month-HDL cholesterol = −0.01
Beresford et al.[37]	RCT *n* = 242 33% minority ≥18 years M = 43 years	Primary care (United States) NR	C: Usual care I: Self-help materials and booster call by nurse 10 days later	3 months	Fat and fiber	Daily fat intake and energy decreased between baseline and FU in both groups. Daily fiber intake decreased in C, whereas fiber intake increased in I	fat = 0.10 fiber = 0.08
Beresford et al.[38]	RCT *n* = 2121 68% women 8% minority	Primary care (United States) TTM	C: Usual care I: Self-help booklet, doctor endorsement, 2-week reminder letter from doctor	3 and 12 months	Fat and fiber	Both groups at 3- and 12-month FU decreased fat intake and increased fiber intake; I showed greater decrease in fat intake and increase in fiber intake	3 months, average fat = 0.07 12 months, average fat = 0.11 3 months, average fiber = 0.01 12 months, average fiber = 0.04
Caggiula et al.[39]	RCT *n* = 930 60% women 19% minority M = 54 years Patients had high cholesterol	Primary care (United States) NR	C: Usual care I_1: Physicians training in dietary counseling and hypercholesterolemia I_2: Physicians identified patients with high serum cholesterol and referred them to nutrition center for treatment	NR	Total serum cholesterol	In patients who were not taking lipid-lowering meds, significant mean decrease in serum cholesterol levels from baseline to FU were seen in both I_1 (0.31 mmol/L or 4.6%) and I_2 (0.54 mmol/L or 7.7%), $P < 0.05$	I_2 versus C = 0.20 I_1 versus C = 0.09

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Diet Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Campbell et al.[40]	RCT n = 558 75% women 19% minority M = 40.8 years	Family practices (rural and urban) (United States) TTM, IIBM	C: No intervention I_1: Sent nutrition information packet tailored to TTM, dietary intake, and psychosocial information I_2: Sent standard risk information and dietary recommendations	4 months	Fat	Total fat decreased by 23% in I_1 versus 9% in I_2, and 3% in C (P <0.10). Saturated fat decreased by 26% in I_1, 11% in I_2, and 3% in C (P <0.05)	I_1 versus C, fat = 0.16 I_2 versus C, fat = 0.04 I_1 versus C, saturated fat = 0.18 I_2 versus C, saturated fat = 0.05
Cohen et al.[41]	RCT n = 30 73% women 20–75 years M = 59.5 years Patients were hypertensive and obese	Family practice (United States) BM	C: Usual care I: Resident training in weight reduction and nutrition education (e.g., lowering calorie intake). Patients consultation and monthly visits	6 and 12 months	Weight	From baseline to 6 months, weight decreased in I but increased in C (–1.8 versus 0.56 kg, P < .004). From 6 to 12 months, weight increased in both groups (0.94 versus 0.73 kg, P >0.10). From baseline to 12 months, weight decreased in I but increased in C (–0.88 versus 1.3 kg, P = 0.10)	6 months = 0.37 12 months = 0.29
Evans et al.[42]	RCT n = 254 68% women 43% minority 20–79 years Patients had high cholesterol	Community and university medical centers (United States) NR	C: Usual care I_1: Resident physician training I_2: Resident physicians were prompted with a fingerstick serum cholesterol determination prior to patient's clinic visit I_3: I_1 + I_2	10 months	Dietary change attempts, total serum cholesterol	Patients of I_2 and I_3 residents had greater knowledge of their elevated cholesterol levels than I_1 or C residents, and were more likely to report trying to change their diet (P = 0.005). Decreases in serum cholesterol did not differ by group	Dietary change attempts = 0.18 cholesterol = 0.05
Glasgow et al.[43]	RCT n = 206 61% women ≥40 years M = 62 years Patients were diabetic	Primary care (United States) NR	C: Usual care I: Personalized counseling, self-help materials to produce individualized goal setting, and video addressing barriers. Telephone FU at 1 and 3 weeks. Three-month FU intervention sequence repeated	12 months	Fat, BMI, total serum cholesterol	Kcal/day decreased from 1740 to 1547 in I, 1761 to 1659 in C, P <0.05. Percent fat decreased from 33.8 to 30.5 in I, 32.9 to 32.0 in C, P <0.03. Percent saturated fat decreased from 11.2 to 9.7 in I, 10.8 to 10.7 in C, P <0.005. Serum cholesterol decreased from 217 to 208 in I, 223 to 226 in C, P <0.005. BMI did not change in I or C	Dietary energy = 0.14 average fat = 0.20 BMI = 0.03 cholesterol = 0.22
Hyman et al.[44]	RCT n = 123 75% women 80% minority 18–65 years M = 56.7 years	Public community health centers (United States) SCT	C: Usual care (brief physician counseling) I: Diet assessment, computer-interactive phone calls, four 1-hour classes	6 months	Fat, weight, total serum cholesterol	Serum cholesterol decreased in I from 273.2 mg/dL to 265.0 mg/dL (P = 0.05). For C, serum cholesterol decreased from 272.1 mg/dL to 267.6 mg/dL (P = 0.32). Fat score and weight decreases between groups were NS	Cholesterol = 0.04 fat = 0.01 weight = 0.01

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Diet Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Jack et al.[45]	QE *n* = 4836 76% women 20–65 years M = 33 years	Family medicine (United States) NR	I: Residents training in serum fingerstick cholesterol screening, diet assessment, and counseling, and FU protocol	Baseline versus 1 year	Total serum cholesterol	The percent of patients screened increased from 16% to 23% (P <0.05). Mean cholesterol decreased from 5.36 to 5.08 mmol/L (P = 0.003)	Total cholesterol = 0.10
Keyserling et al.[46] *n* = 372 51% minority	RCT community and rural health centers 67% women (United States) NR M = 56 years Patients had high cholesterol and low income	Low-income I: Dietary risk assessment, clinician counseling, and culturally specific patient education materials. Referrals to dietitian or health educator or prompt for drug therapy if cholesterol remained elevated	C: Usual care	4, 7, and 12 months	Dietary Risk Assessment, total and HDL serum cholesterol	Patients not taking lipid-lowering medication: serum cholesterol decreased more in I than C at 4 months (–0.28 versus –0.14 mmol/L, P <0.05), and 7 months (–0.27 versus –0.09 mmol/L, P <0.05), but not 12 months. LDL cholesterol decreased more in I than C at 7 months (–0.26 versus –0.09 mmol/L, P <0.05), but differences at 4 and 12 months were NS. Dietary scores improved more in I than C patients at 4 months (–5.5 versus –1.9, P <0.05) and 12 months (–5.4 versus –2.2, P <0.05)	4-month-total cholesterol = 0.11 7-month-total cholesterol = 0.14 12-month-total cholesterol = 0.07 4-month-LDL cholesterol = 0.09 7-month-LDL cholesterol = 0.14 12-month-LDL cholesterol = 0.10 4-month-diet = 0.24 12-month-diet = 0.22
Ockene et al.[47]	RCT *n* = 1162 66% women 20–65 years M = 49.3 years Patients were dyslipidemic	Internal medicine (United States) Patient-centered	C: Usual care I_1: Physician nutrition counseling training I_2: Physician nutrition counseling training plus office support	12 months	Fat; weight; total, LDL, and HDL cholesterol	Compared with C, I_2 decreased fat 1.6%, (P <0.01), decreased weight 2.3 kg (P <0.001), and decreased LDL cholesterol 0.10 mmol/L (3.8 mg/dL) more	I_1 versus C average fat = 0.03 I_2 versus C average fat = 0.10 I_1 versus C weight = 0.03 I_2 versus C weight = 0.07 I_1 versus C cholesterol = –0.02 I_2 versus C cholesterol = 0.10 I_1 versus C LDL = –0.02 I_2 versus C LDL = 0.08 I_1 versus C HDL = 0.05 I_2 versus C HDL = 0.05

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Diet Interventions							
Rhodes et al.[48]	RCT *n* = 100 51% women 6% minority 30–65 years M = 47.6 years Patients had high cholesterol	Outpatient clinics (United States) NR	C: Usual care (10-minute dietary instruction based on NCEP diet sheet) OR usual care + grocery shopping guide I_2: Comprehensive consultation with dietitian OR comprehensive consultation with dietitian and two added consultations	3 months	Dietary energy; fat; total, LDL, and HDL cholesterol	BMI decreased greater in I_2 versus C (1.1 versus 0.6), P <0.001. Both groups decreased dietary energy, but group differences were NS (419 versus 343 for I_2 versus C). Percent fat decreased greater in I_2 versus C patients (9 versus 6), P <0.001. Both groups decreased total serum cholesterol (10% versus 7% decrease for I_2 versus C) and LDL cholesterol (11% versus 9% decrease for I_2 versus C), but group differences were NS	BMI = 0.31 kcal = 0.19 fat = 0.33 cholesterol = 0.15 LDL = 0.10 HDL = 0.09
Combined Interventions							
Cupples & McKnight[49]	RCT *n* = 688 26% women 38–74 years M = 63.1 years Patients had angina	General practice (Ireland) NR	C: No health education I: Patients given advice regarding CVD risk factors. Patients reviewed and given health education at four monthly interviews	24 months	Episodes of PA/week, fiber, saturated fat, SBP, DBP, serum cholesterol, BMI	At FU, more I (44%) than C (24%) exercised 7+ times/week, P <0.0001, and increased exercise (34% versus 21%), P <0.0001. Diet improved more in I than C. Differences between groups were NS for SBP, DBP, cholesterol, and BMI	Average PA = 0.23 fiber = 010 saturated fat = 0.10 insufficient data to compute *r* for SBP, DBP, cholesterol, and BMI
Cupples & McKnight[50]	RCT *n* = 688 26% women 38–74 years M = 63.1 years Patients had angina	General practice (Ireland) NR	C: No health education I: Patients given advice regarding CVD risk factors. Patients were reviewed and given health education at four monthly interviews	24 and 60 months	Episodes of PA/week, diet composite, SBP, DBP, serum cholesterol, BMI	Episodes of PA increased from baseline to 2-year FU for I (3.6 to 4.0) more than C patients (3.8 to 3.2), P <0.001. Diet improved from baseline to 2-year FU more in I (21.1 to 23.7) than C (21.1 to 22.1), but differences were NS at 5-year FU. Group differences in changes from baseline to 2- and 5-year FU for SBP, DBP, cholesterol, and BMI were NS	PA, 2 year = 0.20 PA, 5 year = 0.05 diet, 2 year = 0.19 diet, 5 year = 0.05 SBP, 2 year = -0.05 SBP, 5 year = 0.02 DBP, 2 year = -0.02 DBP, 5 year = 0.05 cholesterol, 2 year = -0.04 cholesterol, 5 year = -0.03 BMI, 2 year = -0.03 BMI, 5 year = -0.02

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Combined Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Dowell et al.[51]	QE *n* = 5624 28–67 years	General practice (United Kingdom) NR	C: No health check I_1: Health check in year 1 I_2: Health check in year 2 I_3: Health checks in years 1 and 2	12 and 24 months	Vigorous exercise, diet score, weight	Differences were NS for increased vigorous exercise or diet. More I_3 lost ≥7 lbs (18%) than C (11%), I_1 (10%), or I_2 (14%), $P = 0.01$. Mean weight loss between groups was NS	Vigorous exercise = 0.01 diet = 0.02 weight loss = 0.03
Family Heart Study Group[52]	RCT *n* = 12,472 40% women 35–61 years M (women) = 49 years M (men) = 51.5 years	General practice (United States) NR	C: Screened at 1-year FU I: Assessment and feedback regarding CVD risk; booklet to document lifestyle changes, and pamphlets. High-risk patients invited for FU (1 time/month, 3 months)	12 months	Serum cholesterol, SBP, DBP, weight	For women: I made greater improvements than C at 12-month FU: decreased total cholesterol (5.61 versus 5.48 mmol/L), SBP (131 versus 123 mm Hg), DBP (81 versus 79 mm Hg), and weight (66.83 versus 66.06 kg)	For women: cholesterol = 0.02 SBP = 0.09 DBP= 0.05 weight = 0.04
Imperial Cancer Research Fund OXCHECK Study Group[53]	RCT *n* = 6124 56% women 35–64 years M = 49 years	General practice (United Kingdom) NR	C: Scheduled for a health check I: Nurse provided a health check and counseled patients about CVD risk factors (M = 44-minute visit)	12 months	Vigorous exercise <1 time/month, diet, serum cholesterol, SBP, DBP, BMI	For women: Fewer I reported <1 exercise session/month than C (65.8% versus 69.4%), $P < 0.05$. Fewer I drank full-cream milk or used butter/hard margarine than C, $P < 0.05$. Cholesterol was lower in I than C (6.00 versus 6.20), $P < 0.05$. SBP was lower in I than in C (122.3 versus 125.7), $P < 0.05$. DBP was lower in I than C (73.2 versus 74.9), $P < 0.05$. BMI differences between groups were NS	For women: vigorous exercise = 0.04 average of butter and full-cream milk = 0.11 cholesterol = 0.07 SBP = 0.08 DBP = 0.07 BMI = 0.02
Imperial Cancer Research Fund OXCHECK Study Group[54]	RCT *n* = 4121 55% women 35–64 years M = 49 years	General practice (United Kingdom) NR	C: Scheduled for a health check I: Nurse provided a health check and counseled patients about CVD risk factors (M = 44-minute visit)	36 months	Vigorous exercise <1 time/month, diet, serum cholesterol, SBP, DBP, BMI	For women: Differences between groups for exercise sessions/month were NS. Fewer I used full-cream milk (20.1%) than C (26.7%), $P < 0.05$, and fewer used butter or hard margarine (20.7% versus 29.2%, $P < 0.05$). Total cholesterol was lower in I than C (5.98 versus 6.26), $P < 0.05$. SBP lower in I than C (124.7 versus 127.0), $P < 0.05$. DBP lower in I than C (74.3 versus 76.0, $P < 0.05$). BMI differences between groups were NS	For women: vigorous exercise = 0.02 average of butter and full-cream milk = 0.09 cholesterol = 0.11 SBP = 0.06 DBP = 0.07 BMI = 0.03

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Combined Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Kelly[35]	RCT *n* = 264 70% women 3% minority 18–60 years	Family practice (United States) NR	C: Usual care I_1: Risk assessment, physician counseling, lifestyle prescription, and educational materials; I_2: Risk assessment, nurse provided educational materials; I_3: Risk assessment only	4 weeks	Behavior change, intent to change	Overall, C had significantly less interest in changing and made significantly fewer changes than I. I_1 made more changes than I_2 and I_3 patients (NS)	Owing to the lack of specificity in outcomes, *r* not computed
Lindholm et al.[36]	RCT *n* = 681 15% women 30–59 years M = 48 years Patients had high cholesterol + two CVD risk factors	Health centers (Sweden) NR	C: Usual care (brief physician counseling for CVD risk reduction) I: Brief physician counseling, six group sessions led by doctor or nurse, videos	18 months	Fat, fiber, exercise, serum cholesterol, BMI, SBP, DBP	Greater changes in I compared with C. Difference between I and C in decreasing serum cholesterol was –0.15 mmol/L (P <0.05), –0.10 mmol/L for LDL, –0.09 for BMI, –1.2 mm Hg for SBP, and –0.10 mm Hg for DBP	Exercise = 0.00 total cholesterol = 0.11 LDL = 0.07 HDL = 0.04 BMI = 0.03 SBP = 0.05 DBP = 0.0
Logsdon et al.[37]	QE *n* = 2128 45.3% women 2.8% minority ≥18 years	Multispecialty practices (United States) NR	C: Usual care I: Physician behavioral risk factor screening and counseling	12 months	Vigorous exercise ≥1 time/week, weight loss	Of those doing no vigorous exercise at baseline, 31.5% of I versus 24.1% of C started exercising at FU, P <0.10. Of those overweight at baseline, 36.6% of I versus 24.8% of C lost ≥5 lbs at FU, P <0.01	Vigorous exercise = 0.08 weight loss = 0.12
Rosamond et al.[38] WISEWOMAN working group[39]	QE *n* = 1957 100% women 41% minority M = 63 years Patients had low income	Nationwide Breast & Cervical Cancer Early Detection Program sites (United States) TTM, SCT, BM	I_1: Delivery of the "New Leaf" program in three in-person intervention counseling sessions. Diet and PA recommendations, goal setting, cookbook, tailored tip sheets, and nontailored tip sheets I_2: Comprehensive health history and CVD risk assessment. Referrals and counseling as indicated	6 and 12 months, 7 months for PA and diet	Percent of people active, Dietary Risk Assessment, BMI, SBP, DBP, i.e., total and HDL cholesterol	Percent active increased in both I_1 and I_2 patients (5.9% versus 9.3% increase, P <0.05), but differences between groups were NS. Dietary improvements seen in the I_2 patients only, P< 0.05. Total cholesterol, SBP, and DBP decreased in both groups at 6 and 12 months, differences between groups were NS. BMI decreased at 6 and 12 months for I_2 patients only (–0.3 and –0.2, P <0.05)	PA, I_1 Δ, 7 months = 0.12 PA, I_2 Δ, 7 mos = 0.19 Diet, I_1 Δ, 7 months = 0.31 Diet, I_2 Δ, 7 months = 0.00 cholesterol, I_1 Δ, 6 months = 0.21 cholesterol, I_2 Δ, 6 months = 0.12 cholesterol, I_1 Δ, 12 months = 0.21 cholesterol, I_2 Δ, 12 months = 0.18 HDL, I_1 Δ, 6 months = –0.10 HDL, I_2 Δ, 6 months = –0.01

Table 1. Summary of Physical Activity, Diet, and Combined Interventions Conducted in Health Care Settings (continued)

Combined Interventions

Study	Design & Sample	Setting & Theory	Intervention	Follow-up	Dependent Variables	Results	Effect Size *r*
Rosamond et al.[58] (continued)							HDL, I_1 Δ, 12 months = 0.09 HDL, I_2 Δ, 12 months = 0.09 SBP, I_1 Δ, 6 months = 0.04 SBP, I_2 Δ, 6 months = 0.07 SBP, I_1 Δ, 12 months = 0.10 SBP, I_2 Δ, 12 months = 0.13 DBP, I_1 Δ, 6 months = 0.11 DBP, I_2 Δ, 6 months = 0.13 DBP, I_1 Δ, 12 months = 0.12 DBP, I_2 Δ, 12 months = 0.12 BMI, I_1 Δ, 6 months = 0.16 BMI, I_2 Δ, 6 months = 0.07 BMI, I_1 Δ, 12 months = 0.12 BMI, I_2 Δ, 12 months = 0.00
Steptoe et al.[60]	RCT *n* = 883 54% women 46.7 years Patients had 1+ modifiable CVD risk factor	General practice (United Kingdom) TTM	C: Usual care I: Behavioral counseling by nurses. Patients were invited for three brief counseling sessions if they had two risk factors, and one session if they had one risk factor. Patients were contacted once or twice by telephone to encourage behavior change	4 and 12 months	Sessions of activity in past 4 weeks, fat, BMI, weight, serum cholesterol, SBP, DBP	Relative to baseline, exercise sessions increased at 4 and 12 months more in I (33.2% and 146%) than C (13.5% and 88.8%), P <0.05. Fat scores improved at 4 and 12 months more in I (26% and 23.3%) than C (11.5% and 15.2%), P <0.05. Differences between groups were NS for BMI, weight, SBP, DBP, and cholesterol	PA 4 months = 0.12 PA 12 months = 0.12 fat 4 months = 0.12 fat 12 months = 0.09 BMI 4 months = 0.04 BMI 12 months = 0.04 SBP 4 months = 0.08 SBP 12 months = 0.08 DBP 4 months = 0.05 DBP 12 months = –0.01 cholesterol 12 months = –0.01

Note: Positive effect sizes refer to a superiority of the intervention group(s) on the variable of interest (or a positive change on the variable of interest for pre-post designs). Abbreviations (in alphabetical order): BM = behavior modification; BMI = body mass index (kg/m^2); C = comparison or control group; CVD = cardiovascular disease; DBP = diastolic blood pressure; FU = follow-up; HBM = Health Belief Model; HDL = high-density lipoprotein; HET = Health Education Theory; I = Intervention group; LDL = low-density lipoprotein; M = mean; MI = motivational interviewing; NR = not reported; NS = not significant; PA = physical activity; PASE = Physical Activity Scale for the Elderly; POMI = Process/Outcome Model for Intervention; QE = quasi-experimental; RCT = randomized clinical trial; SBP = systolic blood pressure; SCT = Social Cognitive/Learning Theory; TTM = Transtheoretical Model.

tive papers of interventions included in our review, three reported on the same population at different follow-up points, two reported only comparisons between two different types of interventions, and one did not distinguish the type of outcome. Thus, correlation coefficients from 32 unique interventions were available for analysis. Eleven studies included PA-only interventions, 13 included diet-only interventions, and eight included combined interventions. From these 32 interventions, 170 correlation coefficients were computed across the CVD risk factors because many studies contributed multiple correlation coefficients for the same CVD risk factor (e.g., different follow-up periods or different comparison groups, etc.). We chose not to report correlation coefficients weighted by sample size, as is common in meta-analyses, because doing so would over-represent these studies in the effect size estimates.

Correlation Coefficients for CVD Risk Factors

The mean correlation coefficients by each of the CVD risk factors are presented in Table 2. The average effect of treatment was generally small but statistically significant ($P < 0.05$; 95% confidence interval [CI] does not include 0) for PA or exercise ($n = 37$), BMI or body weight ($n = 22$), dietary fat ($n = 21$), SBP ($n = 14$), DBP ($n = 14$), total serum cholesterol ($n = 25$), and LDL ($n = 9$). Correlation coefficients were not statistically significant for PA stage of readiness for change ($n = 5$), energy intake ($n = 2$), general dietary factors ($n = 2$), dietary fiber ($n = 6$), dietary stage of readiness for change ($n = 3$), or HDL ($n = 10$). Means that were computed from a small number of correlation coefficients should be interpreted cautiously.

Moderating Factors (Stratified Analysis)

As is customary in the reporting of effect sizes, we also examined whether correlation coefficients for CVD risk factors (PA or exercise, BMI or weight, dietary fat, SBP, and total serum cholesterol) differed when stratified by important moderating variables: participant age (coded as mean age of sample ≤50 years or >50 years), use of a behavioral theory to guide the intervention (coded as no stated theory or a stated behavioral theory), type of intervention (coded as PA only, diet only, or combined intervention), type of comparison group (coded as usual care, brief counseling, or pre-post design), and follow-up period (coded as <6 months or ≥6 months). The number of correlation coefficients for each stratum is presented in Table 3. Correlation coefficients for CVD risk factors, stratified by moderating factors, are shown in Table 4.

Age. With the exception of SBP, interventions tended to produce larger effects in samples with a mean age of >50 years.

Behavior theory. The most common theories or models were Social Cognitive Theory, the Transtheoretical Model, and behavior modification principles. The use of a behavior theory to guide the intervention did not have a major impact on study effectiveness, although for both BMI and SBP, studies using a behavior theory produced somewhat larger correlation coefficients than studies not reporting the use of a behavior theory. Intervention effects were somewhat larger, however, for dietary fat in studies that did *not* report the use of a behavior theory.

Type of intervention. Diet-only interventions were somewhat more effective in reducing body weight than PA-only or combined interventions. Combined interven-

Table 2. Mean Effect Sizes (*r*) for CVD Risk Factors

CVD Risk Factor	*n*	*r*	95% CI
Physical activity			
Physical activity	37	0.0983	0.0747–0.1220
Stage of change	5	0.0676	–0.2144–0.3496
BMI or weight	22	0.0853	0.0376–0.1331
Diet			
Fat	21	0.1211	0.0851–0.1571
Caloric intake	2	0.2350	–0.9968–1.00
General (not specified)	2	0.1169	–0.7668–1.00
Fiber	6	0.1561	–0.0192–0.3315
Stage of change	3	0.4705	–0.2514–1.00
Blood pressure			
Systolic	14	0.0572	0.0315–0.0829
Diastolic	14	0.0494	0.0170–0.0817
Serum cholesterol			
Total	25	0.0862	0.0520–0.1205
HDL	10	0.0230	–0.0233–0.0692
LDL	9	0.0612	0.0167–0.1057

A positive *r* indicates a favorable intervention outcome, with larger numbers representing larger effects.

Note: CVD = cardiovascular disease, CI = confidence interval, HDL = high-density lipoprotein, LDL = low-density lipoprotein, BMI = body mass index (kg/m^2).

tive papers of interventions included in our review, three reported on the same population at different follow-up points, two reported only comparisons between two different types of interventions, and one did not distinguish the type of outcome. Thus, correlation coefficients from 32 unique interventions were available for analysis. Eleven studies included PA-only interventions, 13 included diet-only interventions, and eight included combined interventions. From these 32 interventions, 170 correlation coefficients were computed across the CVD risk factors because many studies contributed multiple correlation coefficients for the same CVD risk factor (e.g., different follow-up periods or different comparison groups, etc.). We chose not to report correlation coefficients weighted by sample size, as is common in meta-analyses, because doing so would over-represent these studies in the effect size estimates.

Correlation Coefficients for CVD Risk Factors

The mean correlation coefficients by each of the CVD risk factors are presented in Table 2. The average effect of treatment was generally small but statistically significant (P <0.05; 95% confidence interval [CI] does not include 0) for PA or exercise (n = 37), BMI or body weight (n = 22), dietary fat (n = 21), SBP (n = 14), DBP (n = 14), total serum cholesterol (n = 25), and LDL (n = 9). Correlation coefficients were not statistically significant for PA stage of readiness for change (n = 5), energy intake (n = 2), general dietary factors (n = 2), dietary fiber (n = 6), dietary stage of readiness for change (n = 3), or HDL (n = 10). Means that were computed from a small number of correlation coefficients should be interpreted cautiously.

Moderating Factors (Stratified Analysis)

As is customary in the reporting of effect sizes, we also examined whether correlation coefficients for CVD risk factors (PA or exercise, BMI or weight, dietary fat, SBP, and total serum cholesterol) differed when stratified by important moderating variables: participant age (coded as mean age of sample ≤50 years or >50 years), use of a behavioral theory to guide the intervention (coded as no stated theory or a stated behavioral theory), type of intervention (coded as PA only, diet only, or combined intervention), type of comparison group (coded as usual care, brief counseling, or pre-post design), and follow-up period (coded as <6 months or ≥6 months). The number of correlation coefficients for each stratum is presented in Table 3. Correlation coefficients for CVD risk factors, stratified by moderating factors, are shown in Table 4.

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Behavior theory. The most common theories or models were Social Cognitive Theory, the Transtheoretical Model, and behavior modification principles. The use of a behavior theory to guide the intervention did not have a major impact on study effectiveness, although for both BMI and SBP, studies using a behavior theory produced somewhat larger correlation coefficients than studies not reporting the use of a behavior theory. Intervention effects were somewhat larger, however, for dietary fat in studies that did *not* report the use of a behavior theory.

Type of intervention. Diet-only interventions were somewhat more effective in reducing body weight than PA-only or combined interventions. Combined interven-

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Physical activity			
Physical activity	37	0.0983	0.0747–0.1220
Stage of change	5	0.0676	–0.2144–0.3496
BMI or weight	22	0.0853	0.0376–0.1331
Diet			
Fat	21	0.1211	0.0851–0.1571
Caloric intake	2	0.2350	–0.9968–1.00
General (not specified)	2	0.1169	–0.7668–1.00
Fiber	6	0.1561	–0.0192–0.3315
Stage of change	3	0.4705	–0.2514–1.00
Blood pressure			
Systolic	14	0.0572	0.0315–0.0829
Diastolic	14	0.0494	0.0170–0.0817
Serum cholesterol			
Total	25	0.0862	0.0520–0.1205
HDL	10	0.0230	–0.0233–0.0692
LDL	9	0.0612	0.0167–0.1057

A positive r indicates a favorable intervention outcome, with larger numbers representing larger effects.
Note: CVD = cardiovascular disease, CI = confidence interval, HDL = high-density lipoprotein, LDL = low-density lipoprotein, BMI = body mass index (kg/m^2).

Table 3. The Number of Correlation Coefficients (of 119) Representing Each Level of the Moderating Variable for Cardiovascular Disease Risk Factors

Moderating Variable	Number of Correlation Coefficients
Age	
Samples with a mean age ≤50 years	54
Samples with a mean age >50 years	61
Samples that did not report mean age	4
Behavior Theory	
Reported using a behavior theory	61
Did not report using a behavior theory	58
Type of Intervention	
PA-only	30
Diet-only	33
Combined	56
Comparison Groups	
Compared intervention with no treatment or usual care	91
Compared intervention with minimal intervention	10
Pre- and post-comparisons	18
Follow-up Period	
Follow-up period of ≥6 months	85
Follow-up period of <6 months	31

Note: PA = physical activity.

tions were more effective than PA-only interventions in reducing blood pressure. PA-only interventions only measured PA outcomes, and these interventions produced correlation coefficients comparable with combined interventions in increasing PA. In addition, diet-only and combined interventions were equally effective in reducing total serum cholesterol and dietary fat.

Comparison groups. The majority of studies reviewed compared an intervention group with a no-treatment or a usual-care control group, making the examination of correlation coefficients by type of comparison difficult. No consistent pattern in effect size was noted when studies compared an intervention group with a no-treatment control group, an intervention group with a minimal intervention group, or pretreatment with post-treatment scores (not shown in Table 4). The majority of studies used random assignment, with randomization occurring at the level of the patient, health care provider, or clinic/site.

Follow-up period. Several long-term intervention studies included in this review reported on several CVD outcomes at multiple time periods, which contributed to the large number of correlation coefficients for longer-term studies. Intervention effects were generally greater for PA when the follow-up period was <6 months than

Table 4. Mean Effect Sizes (*r*) for Cardiovascular Disease Risk Factors by Moderating Factors

	Physical Activity		BMI or Weight		Dietary Fat		Systolic Blood Pressure		Total Serum Cholesterol	
	n	*r* (95% CI)	*n*	*r* (95% CI)	*n*	*r* (95% CI)	*n*	*r* (95% CI)	*n*	*r* (95% CI)
Mean sample age										
≤50 years	19	0.08* (0.06–0.11)	8	0.07 (–0.01–0.15)	12	0.11* (0.07–0.14)	5	0.07* (0.05–0.09)	10	0.05* (0.01–0.11)
>50 years	17	0.12* (0.07–0.16)	13	0.09* (0.02–0.16)	7	0.15* (0.04–0.26)	9	0.05* (0.01–0.09)	15	0.11* (0.06–0.15)
Behavior theory										
No theory specified	14	0.11* (0.05–0.16)	11	0.06* (0.00–0.12)	8	0.16* (0.10–0.21)	8	0.04* (0.01–0.07)	17	0.08* (0.04–0.12)
Theory specified	23	0.09* (0.07–0.12)	11	0.11* (0.03–0.19)	13	0.10* (0.05–0.15)	6	0.08* (0.05–0.12)	8	0.10* (0.03–0.18)
Type of intervention										
PA-only	26	0.09* (0.07–0.12)	2	0.07 (–0.06–0.20)	0		2	0.03 (–0.13–0.18)	0	
Diet-only	0		7	0.16* (0.01–0.30)	12	0.13* (0.08–0.18)	0		14	0.09* (0.04–0.13)
PA + Diet	11	0.11* (0.05–0.16)	13	0.05* (0.01–0.08)	9	0.11* (0.05–0.17)	12	0.06* (0.03–0.09)	11	0.09* (0.03–0.15)
Follow-up period										
<6 months	14	0.13* (0.09–0.17)	3	0.14 (–0.22–0.50)	9	0.13* (0.08–0.18)	2	0.05 (–0.38–0.47)	3	0.07 (–0.17–0.32)
≥6 months	23	0.08* (0.05–0.11)	19	0.08* (0.03–0.13)	12	0.11* (0.06–0.17)	12	0.06* (0.03–0.09)	19	0.08* (0.04–0.12)

* $P < 0.05$. A positive *r* indicates a favorable intervention outcome, with larger numbers representing larger effects.
Note: CI = confidence interval, PA = physical activity, BMI = body mass index (kg/m²).

when the follow-up period was ≥6 months. Otherwise, effects of shorter- and longer-term follow-up periods were similar. It is important to note, however, that the number of correlation coefficients contributing to BMI, SBP, and total serum cholesterol means for shorter follow-up periods was small, and these findings should therefore be interpreted with caution.

Discussion

Major Findings

To our knowledge, this is the first review to examine the *magnitude* of effects of PA and dietary intervention studies delivered in health care settings. Overall, these interventions tended to produce modest but statistically significant effects for PA or exercise, dietary fat, weight loss, blood pressure, and serum cholesterol. The discipline of study and existing scientific literature should dictate the interpretation of effect size magnitude.[15,16] Whereas small by conventional statistical definitions,[61] these findings are likely to be meaningful when considered from a public health perspective. Clinical settings offer a way to reach a large proportion of the population, especially when low-income community health care clinics are included. CVD risk factors, many of which are reduced by increased PA and improved diet, are prevalent in the United States and other countries.[62] In addition, these effects were seen even though the intensity of interventions reviewed tended to be modest, often involving brief behavioral counseling by a health care provider and printed educational materials. Finally, PA and dietary assessments are subject to considerable measurement error, which attenuates true correlation coefficients. In fact, probably owing to the difficulty of implementing lengthy assessments in health care settings, many of the measures of PA and diet used in these studies were single-item or very brief inventories. The true magnitude of effect is likely to be larger than reported here.

Intervention effects were generally larger for samples with a mean age >50 years. CVD risk factors increase with age and interventions are therefore likely to show a greater impact on the populations most in need of change. In addition, for PA in particular, interventions with <6 months of follow-up tended to have greater effects. This finding is consistent with the commonly reported declines in adherence to PA over time and high dropout rates. It also suggests that the factors and interventions that initially promote PA may be different from those that sustain PA over time, and that health care–based interventions should strive to address behavior maintenance.

The fact that combined interventions had similar effects on total serum cholesterol, PA, and dietary fat as single-behavior interventions is important. It suggests that interventions are not "diluted" when they focus on more than one behavior simultaneously. It was surprising that studies reporting the use of a behavior theory to guide the intervention did not generally lead to stronger effects, except perhaps for weight loss and blood pressure. It is possible that other interventions did, in fact use behavioral principles but the authors of these studies did not specifically report the use of these principles. Alternatively, the brief nature of most of the interventions reviewed might not allow for behavior theories to have a major impact.

Finally, a number of studies were tailored to the participants' stage of readiness for change and included brief follow-up contact (e.g., mailings, telephone contacts). Many of the studies in our review that produced larger correlation coefficients included tailoring to stage of readiness for change or to ethnic group and follow-up contacts.

Interventions with Persons of Color

Of the studies reviewed, the vast majority included a small percentage of persons of color or none at all. In the intervention by Hyman et al.,[44] 80% of the sample was persons of color. The intervention was aimed at reducing dietary fat in two public health clinics. The control group received brief physician dietary counseling, whereas the intervention group received four diet classes and computer-interactive telephone calls. Although the intervention group showed a reduction in serum cholesterol levels, the differences between groups for serum cholesterol, dietary fat, and body weight were not significant.

Two additional interventions that were reviewed, the Southeast Cholesterol Project[46] and the North Carolina WISEWOMAN Project,[38] were conducted with ethnically diverse samples of low-income individuals (51% and 41% of the participants were persons of color, respectively). The Southeast Cholesterol Project used the "Food for Heart Program," which consists of a dietary risk assessment, clinician counseling materials, and culturally specific patient education materials for individuals of low socioeconomic status from the southern United States. This project was conducted in 21 low-income community and rural health centers. Clinicians were randomized to provide either usual care or a dietary intervention that included clinician dietary counseling, culturally specific educational materials, referral to a dietitian at 4 months if cholesterol remained elevated, and referral for drug treatment at 7 months if cholesterol remained elevated. Significant improvements were noted for total serum cholesterol, LDL, and dietary change. Further, correlation coefficients tended to be larger than those reported for our overall review.

Similarly, the North Carolina WISEWOMAN Project was conducted at Breast and Cervical Cancer Early Detection Program sites. This project compared the delivery of

the "New Leaf" program (an enhanced intervention based on the "Food for Heart Program" that included three intervention counseling sessions with printed educational materials) with a minimal intervention (CVD risk assessment, and referrals and counseling as indicated). Thus, this program was also culturally tailored and designed for individuals of low socioeconomic status. Although the enhanced intervention produced larger effects than the minimal intervention for dietary change, the two groups were not significantly different for other CVD outcomes. However, significant pre-post changes in CVD outcomes occurred for both groups, and the correlation coefficients were often larger than reported for our overall review.

Together, these two studies indicate that interventions that target at-risk and underserved groups can produce significant effects when they are tailored to the population of interest. Clearly, more studies are needed to address the effectiveness of PA and dietary counseling delivered in health care settings with financially disadvantaged and ethnically diverse individuals.

Study Limitations

Although a number of benefits to computing effect sizes exist, limitations to the use of effect sizes are well described by Glass and colleagues and summarized by Wolf.[13] First, conclusions drawn by comparing and aggregating studies that include different measuring techniques, definitions of variables, and participants raise difficulties.[13] In our review, the structure and delivery of the interventions varied greatly, as did participants (including by country of residence), and very few studies used the same diet and PA outcome measures. For example, some studies assessed minutes per week exercised, whereas others assessed whether or not the person could be classified as regularly active. These issues were more pronounced than they would be, for example, in drug efficacy studies, where outcomes may be more standard (e.g., blood pressure). Second, meta-analysis techniques have been criticized for mixing "poorly" designed studies with "good" studies, which may attenuate or exaggerate outcomes, depending on the type of threats to validity.[13] In this study, we did not code for study quality. The vast majority of studies were randomized clinical trials, however, rather than quasi-experimental designs. Third, significant findings are more likely to be published than nonsignificant findings, which may bias results. Finally, multiple results from the same study (i.e., results that are not independent) may make the results appear more reliable than they truly are. Although we tried to limit the number of effect sizes in our review by, for example, averaging across different measures of the same construct (e.g., different scales used to assess PA), some studies still contributed multiple effect sizes to the analyses.[13] Finally, if moderating factors are associated (e.g., if diet-only studies also tend to be short term), results of analyses by moderating factors may not provide an accurate description of the role of the moderating factor. Thus, we recommend that to develop an intervention for health care settings, it is prudent to examine the components of the reviewed studies, the participant characteristics, and the outcomes to determine whether the intervention is likely to be feasible and effective.

Summary

This study was unique in that it examined the *magnitude* of the effects of dietary and PA interventions delivered in health care settings in reducing CVD risk factors. Our analyses indicate that these interventions, on average, were effective. Although intervention effects tended to be modest in size according to standard criteria, they were generally statistically significant and likely to be of significance to public health. A nationwide goal is to eliminate gender, ethnic, socioeconomic, and other disparities in health by the year 2010.[2] Health care settings have great potential for helping to reduce disparities in CVD risk factors and outcomes. Most adults visit their health care provider at least once a year.[63] The few studies done to date with persons of color show promising results in reducing CVD risk factors. A common component of these studies is that the interventions are culturally relevant and tailored to the target population. Additional studies conducted in a range of health care settings, serving diverse patient populations, and addressing the longer-term maintenance of health behavior change will be invaluable in better understanding how to improve the health of our nation.

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1. Frame PS, Berg AO, Woolf S. U.S. Preventive Services Task Force: highlights of the 1996 report. Am Fam Physician 1997;55:567–76, 581–62
2. U.S. Department of Health and Human Services. Healthy People 2010: understanding and improving health, 2nd ed. Washington, DC: U.S. Government Printing Office, 2000
3. McGinnis JM, Foege WH. Actual causes of death in the United States. JAMA 1993;270:2207–12
4. Wee CC, McCarthy EP, Davis RB, Phillips RS. Physician counseling about exercise. JAMA 1999;282: 1583–8

5. U.S. Department of Health and Human Services. Physical activity and health: a report of the Surgeon General. Atlanta, GA: National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1996
6. Mosca L, Manson JE, Sutherland SE, et al. Cardiovascular disease in women: a statement for healthcare professionals from the American Heart Association Writing Group. Circulation 1997;96: 2468–82
7. Ashenden R, Silagy C, Weller D. A systematic review of the effectiveness of promoting lifestyle change in general practice. Fam Pract 1997;14: 160–76
8. Marcus BH, Pinto BM, Clark MM, et al. Physician-delivered physical activity and nutrition interventions. Med Exerc Nutr Health 1995;4:325–34
9. Simons-Morton DG, Calfas KJ, Oldenburg B, Burton NW. Effects of interventions in health care settings on physical activity or cardiorespiratory fitness. Am J Prev Med 1998;15:413–30
10. Eaton CB, Menard LM. A systematic review of physical activity promotion in primary care office settings. Br J Sports Med 1998;32:11–6
11. Poynard T, Conn HO. The retrieval of randomized clinical trials in liver disease from the medical literature. A comparison of MEDLARS and manual methods. Control Clin Trials 1985;6:271–9
12. Haynes RB, McKibbon KA, Walker CJ, et al. Computer searching of the medical literature. An evaluation of MEDLINE searching systems. Ann Intern Med 1985;103:812–6
13. Rosenthal R. Meta-analytic procedures for social research. Beverly Hills, CA: Sage, 1984
14. Schwarzer R. Meta-analysis 5.3. Berlin: Free University of Berlin, 1989
15. Wolf FM. Meta-analysis. Quantitative methods for research synthesis. Newbury Park, CA: Sage, 1986
16. Blair SN, Applegate WB, Dunn AL, et al. Activity Counseling Trial (ACT): rationale, design, and methods. Activity Counseling Trial Research Group. Med Sci Sports Exerc 1998;30:1097–106
17. King AC, Sallis JF, Dunn AL, et al. Overview of the Activity Counseling Trial (ACT) intervention for promoting physical activity in primary health care settings. Activity Counseling Trial Research Group. Med Sci Sports Exerc 1998;30:1086–96
18. Bull FC, Jamrozik K. Advice on exercise from a family physician can help sedentary patients to become active. Am J Prev Med 1998;15:85–94
19. Bull FC, Jamrozik K, Blanksby BA. Tailored advice on exercise—does it make a difference? Am J Prev Med 1999;16:230–9
20. Bull FC, Kreuter MW, Scharff DP. Effects of tailored, personalized and general health messages on physical activity. Patient Educ Couns 1999;36:181–92
21. Burton LC, Paglia MJ, German PS, et al. The effect among older persons of a general preventive visit on three health behaviors: smoking, excessive alcohol drinking, and sedentary lifestyle. The Medicare Preventive Services Research Team. Prev Med 1995;24:492–7
22. Calfas KJ, Long BJ, Sallis JF, et al. A controlled trial of physician counseling to promote the adoption of physical activity. Prev Med 1996;25:225–33
23. Goldstein MG, Pinto BM, Marcus BH, et al. Physician-based physical activity counseling for middle-aged and older adults: a randomized trial. Ann Behav Med 1999;21:40–7
24. Pinto BM, Goldstein MG, DePue JD, Milan FB. Acceptability and feasibility of physician-based activity counseling. The PAL project. Am J Prev Med 1998;15:95–102
25. Graham-Clarke P, Oldenburg B. The effectiveness of a general-practice-based physical activity intervention on patient physical activity status. Behavior Change 1994;11:132–44
26. Harland J, White M, Drinkwater C, et al. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. BMJ 1999;319:828–32
27. Kerse NM, Flicker L, Jolley D, et al. Improving the health behaviours of elderly people: randomised controlled trial of a general practice education programme. BMJ 1999;319:683–7
28. Lewis BS, Lynch WD. The effect of physician advice on exercise behavior. Prev Med 1993;22:110–21
29. Marcus BH, Goldstein MG, Jette A, et al. Training physicians to conduct physical activity counseling. Prev Med 1997;26:382–8
30. Naylor PJ, Simmonds G, Riddoch C, et al. Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. Health Educ Res 1999;14:653–66
31. Schultz SJ. Educational and behavioral strategies related to knowledge of and participation in an exercise program after cardiac positron emission tomography. Patient Educ Couns 1993;22:47–57
32. Stevens W, Hillsdon M, Thorogood M, McArdle D. Cost-effectiveness of a primary care based physical activity intervention in 45–74 year old men and women: a randomised controlled trial. Br J Sports Med 1998;32:236–41
33. Swinburn BA, Walter LG, Arroll B, et al. The green prescription study: a randomized controlled trial of written exercise advice provided by general practitioners. Am J Public Health 1998;88:288–91
34. Taylor AH, Doust J, Webborn N. Randomised controlled trial to examine the effects of a GP exercise referral programme in Hailsham, East Sussex, on modifiable coronary heart disease risk factors. J Epidemiol Community Health 1998;52:595–601
35. Ammerman AS, DeVellis BM, Haines PS, et al. Nutrition education for cardiovascular disease prevention among low income populations—description and pilot evaluation-of a physician-based model. Patient Educ Couns 1992;19:5–18
36. Baron JA, Gleason R, Crowe B, Mann JI. Preliminary trial of the effect of general practice based nutritional advice. Br J Gen Pract 1990;40:137–41
37. Beresford SA, Farmer EM, Feingold L, et al. Evaluation of a self-help dietary intervention in a primary care setting. Am J Public Health 1992;82:79–84
38. Beresford SA, Curry SJ, Kristal AR, et al. A dietary intervention in primary care practice: the Eating Patterns Study. Am J Public Health 1997;87:610–6

39. Caggiula AW, Watson JE, Kuller LH, et al. Cholesterol-lowering intervention program. Effect of the step I diet in community office practices. Arch Intern Med 1996;156:1205–13
40. Campbell MK, DeVellis BM, Strecher VJ, et al. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. Am J Public Health 1994;84:783–7
41. Cohen MD, D'Amico FJ, Merenstein JH. Weight reduction in obese hypertensive patients. Fam Med 1991;23:25–8
42. Evans AT, Rogers LQ, Peden JG Jr, et al. Teaching dietary counseling skills to residents: patient and physician outcomes. The CADRE Study Group. Am J Prev Med 1996;12:259–65
43. Glasgow RE, La Chance PA, Toobert DJ, et al. Long-term effects and costs of brief behavioural dietary intervention for patients with diabetes delivered from the medical office. Patient Educ Couns 1997;32:175–84
44. Hyman DJ, Ho KS, Dunn JK, Simons-Morton D. Dietary intervention for cholesterol reduction in public clinic patients. Am J Prev Med 1998;15:139–45
45. Jack BW, Gans KM, McQuade W, et al. A successful physician training program in cholesterol screening and management. Prev Med 1991;20:364–77
46. Keyserling TC, Ammerman AS, Davis CE, et al. A randomized controlled trial of a physician-directed treatment program for low-income patients with high blood cholesterol: the Southeast Cholesterol Project. Arch Fam Med 1997;6:135–45
47. Ockene IS, Hebert JR, Ockene JK, et al. Effect of physician-delivered nutrition counseling training and an office-support program on saturated fat intake, weight, and serum lipid measurements in a hyperlipidemic population: Worcester Area Trial for Counseling in Hyperlipidemia (WATCH). Arch Intern Med 1999;159:725–31
48. Rhodes KS, Bookstein LC, Aaronson LS, et al. Intensive nutrition counseling enhances outcomes of National Cholesterol Education Program dietary therapy. J Am Diet Assoc 1996;96:1003–10
49. Cupples ME, McKnight A. Randomised controlled trial of health promotion in general practice for patients at high cardiovascular risk. BMJ 1994;309:993–6
50. Cupples ME, McKnight A. Five year follow up of patients at high cardiovascular risk who took part in randomised controlled trial of health promotion. BMJ 1999;319:687–8
51. Dowell AC, Ochera JJ, Hilton SR, et al. Prevention in practice: results of a 2-year follow-up of routine health promotion interventions in general practice. Fam Pract 1996;13:357–62
52. Family Heart Study Group. Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. BMJ 1994;308:313–20
53. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. BMJ 1994;308:308–12
54. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. BMJ 1995;310:1099–104
55. Kelly RB. Controlled trial of a time-efficient method of health promotion. Am J Prev Med 1988;4:200–7
56. Lindholm LH, Ekbom T, Dash C, et al. The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. BMJ 1995;310:1105–9
57. Logsdon DN, Lazaro CM, Meier RV. The feasibility of behavioral risk reduction in primary medical care. Am J Prev Med 1989;5:249–56
58. Rosamond WD, Ammerman AS, Holliday JL, et al. Cardiovascular disease risk factor intervention in low-income women: the North Carolina WISEWOMAN project. Prev Med 2000;31:370–9
59. The WISEWOMAN Workgroup. Cardiovascular disease prevention for women attending breast and cervical cancer screening programs: the WISEWOMAN projects. Prev Med 1999;28:496–502
60. Steptoe A, Doherty S, Rink E, et al. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. BMJ 1999;319:943–7
61. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale, NJ: Lawrence Erlbaum, 1988
62. American Heart Association. 2000 Heart and stroke statistical update. Dallas, TX: American Heart Association, 1999
63. U.S. Department of Health and Human Services. Health, United States, 1999. Health and aging chartbook. Rep. 76-641496. Washington, DC: U.S. Government Printing Office, 1999

Appendix L

Logic Model Describing WISEWOMAN

Describing the WISEWOMAN Program